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SUBSTITUTE CHEMICAL PROGRAM - THE FIRST YEAR OF PROGRESS

PROCEEDINGS OF A SYMPOSIUM

Volume I

Plenary Session

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SHERATON-FREDERICKSBURG MOTOR INN
FREDERICKSBURG, VIRGINIA

JULY 30 - AUGUST 1, 1975

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The Proceedings of the SUBSTITUTE CHEMICAL PROGRAM -- THE FIRST YEAR OF PROGRESS are published in four volumes. Volume I contains speeches and discussion from the Plenary Session, the agenda, and lists of participants and speakers. Volumes II, III, and IV cover the Toxicological Methods and Genetic Effects Workshop, the Ecosystems/ Modeling Workshop, and the Chemical Methods Workshop, respectively.

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WELCOME

Dr. William Roessler*

Many of you were present at the symposium held in Denver just one year ago. At that time we looked at the Program; we focused on the purpose, the organization, the operations of the Program; we examined pesticide research needs; we thought of pesticides even on an international scale; and we attempted to look at the future, because we were just launching a program.

This morning I bring to you greetings from Dr. Leonard Axelrod, Director of the Criteria and Evaluation Division, and from Dr. John Buckley, sometimes referred to as Mr. Pesticides of the Office of Research and Development. Neither of these gentlemen is here at the present time, although Dr. Buckley is scheduled to join us in a few hours.

Dr. Axelrod will not be with us to look at the first year of progress, and it is unfortunate that he is not here to light the candle on the birthday cake for the 1-year-old Program that he and Dr. Buckley envisioned and nurtured through these past few months. (Editor's note: Dr. Axelrod suffered a fatal cardiac seizure on the first day of the conference.)

It has been an important year, and I believe we've made a good start. We are recognized for what we are attempting to do. Those of you who read the Washington Post know that even the Post recognized the importance of the Program in an editorial just this past week. I won't comment on the rest of the editorial, however. The Program is an example of how Government, industry, and academia can work together toward common goals.

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*Deputy Director, Criteria and Evaluation Division, EPA

To reiterate the four principal objectives of the Program in the words of Dr. Axelrod a year ago: The first is to identify suitable substitutes -- sometimes we use the word alternatives -- insofar as possible for products and/or uses, both major and minor which (a) are under internal review and therefore possible candidates for cancellation, (b) are in litigation for cancellation or suspension, or (c) have been cancelled or suspended. The second involves studies to develop reliable, and hopefully economically feasible screening methodologies for evaluating pesticides under review in the areas of toxicology and safety, where there is such a need, as for example with the "genesis" and reproductive problems associated with exposure to pesticides. The third is to do research filling certain gaps of knowledge in the areas of toxicology, ecology, and chemistry needed to flesh out the data bases for the review of suitable substitutes. The fourth is to stimulate, through liaison efforts with industry, the research and development required to register new pesticides in specific areas of the agricultural sector needed as suitable substitutes.

Many of you have made substantive contributions to the Program, and all of us are looking forward to the second year and beyond, particularly when we think about research. Research is the main theme of this 3-day meeting. We have a very interesting and full program and the workshops should be stimulating. We have the opportunity to become better acquainted with one another, and we should come away from this meeting with a better understanding of how we individually, collectively, and, surely, cooperatively can fulfill the objectives of the Program. I urge all of you to participate -- to be involved in the discussions so that we can bring into proper focus our available expertise, energy, and other resources so that a year from now we can look back at an even more successful year.

So my welcome is more than a welcome. It is a challenge for the next year. This, I am sure, comes from Mr. Russell Train, the Administrator, and his staff, through Mr. Jim Agee, the Assistant Administrator, Mr. Ed Johnson, the Deputy Assistant Administrator for Pesticides Programs, all the way down to the real people in the Office of Pesticides Programs, such as you and those who are dealing very closely with the problems at hand. So I say welcome to all of you.

INTRODUCTION

Kenneth Olsen*

EPA's Substitute Chemical Program was initiated in the spring of 1974. Its purpose was delegated by a Congressional mandate to provide for research, testing, and subsequent evaluation of substitute pesticides to insure that those pesticides that replaced cancelled or suspended uses of registered pesticides do not in fact create greater problems with respect to human health and the environment.

The Program was funded by a $5-million, 50-position appropriation in FY-74 under Public Law 93-135. It has been continued at that level for FY-75 and FY-76 within EPA's annual budget submission to Congress. This conference has been titled the Substitute Chemical Program -- The First Year of Progress. Its purpose is to present the results of the Agency's effort since our first major conference held last August in Denver, which many of you attended.

That conference presented in detail our planning effort for the Program. This meeting, just about one year later, will report on the implementation of those plans. As you all probably know, Governmental agencies receive their funding appropriation on a fiscal year basis. These funds are unfortunately not available on July 1 of that year for the scientists to immediately utilize due to Congressional hearings (which are still going on with respect to the FY-76 budget), OMB transfer, normal agency allocation times, and, with respect to extramural work, contract and grant delays in advertisement and evaluation. Therefore, most of the results that will be presented in scientific workshops were funded by the FY-74 appropriation. These programs have been underway for at least one year.

The work initiated under the FY-75 appropriation will be reported as ongoing programs, many of which are only a few months old. It was felt that even though

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*Criteria and Evaluation Division, EPA

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no substantive results can be presented for these FY-75 programs, they should be discussed to provide the individual scientists in attendance with an insight into the thrust and direction of all the Program's scientific efforts.

Due to the quantity of projects within the Substitute Chemical Program, the conference had to be subdivided into three breakout sessions. The Toxicological Methods and Genetic Effects Workshop, co-chaired by Dr. L. B. Dale of the Office of Pesticide Programs, Criteria and Evaluation Division, and Dr. August Curley of the Office of Research and Development, Research Triangle Park, will be held in this room. Twenty-nine projects will be presented and discussed.

The Ecosystems/Modeling Workshop will be co-chaired by Dr. John Buckley and Dr. Norman Glass of the Office of Research and Development. Twelve projects will be presented in this workshop.

In the Chemical Methods Workshop, co-chaired by Dr. Ed Oswald of the Office of Research and Development, Research Triangle Park, and Dr. Gunter Zweig of the Office of Pesticide Programs, Criteria and Evaluation Division, 13 projects will be presented.

With the exception of only a very few, all of the projects that will be discussed in the workshops have been funded by the Substitute Chemical Program's appropriation. All scientific projects that will be discussed fall into three general categories, some of which overlap. The first we can define as scientific and economic data collection to fill specific knowledge gaps identified as necessary to evaluate the safety and efficacy of potential substitute chemicals. These studies are usually carried out by existing, accepted protocols. Secondly, the development of new techniques, methodologies, and protocols to increase the Agency's capability to evaluate potential substitute chemicals and, thirdly, the development of rapid screening techniques to improve the speed and sometimes the accuracy of evaluating the safety of several potential substitute chemicals.

I would like to encourage a free and open scientific interchange between the personnel in these workshops. All the speakers are EPA laboratory scientists performing the actual experiments, EPA technical contract project officers, scientists from other Governmental agencies working on interagency agreements, or contractor laboratory scientists actively involved in the individual projects discussed.

This morning's session will provide a synopsis of the organization and management of the Program within EPA. In addition, the status of the reviews of potential substitute chemicals will be discussed. Not much has changed with respect to Program management since the Program's plans were presented last August in Denver; therefore, we will not consume too much time with them. However, we'll briefly review them to get everyone up to speed with respect to purpose and intent of the Program.

Finally, other topics scheduled for the general sessions tomorrow afternoon and Friday morning are interdisciplinary. We felt they were of general enough interest that they should be scheduled to enable everyone to have a chance to hear them.

PROGRAM OVERVIEW AND REVIEW PROCESS

Kenneth Olsen*

The purpose of the Substitute Chemical Program is to determine the adequacy and suitability from both safety and efficacy viewpoints of substitute pesticides to act as replacements for uses of other pesticides considered problematic (suspect) by the Agency.

A problem or suspect pesticide is defined as one that has had some or all of its uses cancelled or suspended, is in litigation, or is under internal review for potential unreasonable adverse effects to man or the environment.

Most of the potential substitutes that are now or will be evaluated by the Program are currently registered pesticides that have the same use registration(s) as a problem or suspect chemical. Where warranted, pesticides not currently registered for a particular use in question will be considered that have the potential as substitutes. Examples of these are pheromones, juvenile hormones, viruses, and other conventional pesticides requiring a new use registration.

EPA's regulatory authority which defines a problem or suspect chemical is stated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, Sections 6(b)1 or 6(b)2. The first suspect chemical looked at under the Substitute Chemical Program was DDT. We are now analyzing several others and you'll be hearing about those shortly.

The Program has three general areas: the review process, liaison efforts, and research efforts.

- Subplan A: Substitute Chemical Program Review Process -- Evaluates the suitability of pesticide chemicals to act as substitutes for problematic (suspect) chemicals.

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*Criteria and Evaluation Division, EPA

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- Subplan B: Liaison -- Interchange of information between EPA, industry, other agencies, and academia.
- Subplan C: Research -- Develop data to support the review process and new techniques for evaluating the safety of substitute pesticides.

Reviews of the potential substitute chemicals are primarily the responsibility of the Criteria and Evaluation Division of the Office of Pesticide Programs. This process will be covered in more detail in the next presentation.

Liaison is covered at many levels, from individual meetings with a particular registrant to an annual conference such as this one. Also smaller scientific and economic conferences are held throughout the year on specific topics as the need arises. Research is primarily the responsibility of EPA's Office of Research and Development. At least 75 percent of all funds expended in this area are expended by that Office. In special cases in which unique individual capability exists within the Criteria and Evaluation Division, a C&E project officer is assigned to a program. All projects reported in the three scientific workshops will fall under this Subplan C. Also very close cooperation is maintained between the Office of Research and Development and the Criteria and Evaluation Division throughout the year, and we anticipate this will continue in FY-76.

Little time was spent at last year's conference with respect to the actual research results being obtained under the Program. This conference has been organized to emphasize the research and special study aspects of the Substitute Chemical Program. The various EPA organizational components that are actively participating in the Program are listed below.

Office of Pesticide Programs	Office of Research and Development
Criteria and Evaluation Division	Headquarters
Program Coordination	Research Management
SCP Reviews	
Liaison	
Special Studies	

Office of Pesticide Programs (cont'd)

Registration Division
  Data to Support Reviews
  Use of Reviews as Data Bases

Technical Services Division
  Monitoring Data

Operations Division
  Accident Reports

EPA Regions

State and Local Pesticide Use Recommendations

Identification of Critical Uses

Office of Research and Development (cont'd)

Health Effects Research Lab, RTP
  Toxicological Research
  Methods Development
  Pesticide Chemicals Repository

Environmental Research Lab, Corvallis
  Terrestrial Ecosystems
  Microcosm Development

Environmental Research Lab, Duluth
  Fresh Water Ecosystems

Environmental Research Lab, Gulf Breeze
  Marine/Estuary Ecosystems
  Microcosm Development

Environmental Research Lab, Athens
  Environmental Chemistry Ecosystems
  Development

Under the Office of Pesticide Programs, which is headed by Deputy Assistant Administrator Ed Johnson, we have four divisions, and each of these divisions is participating to some degree within the Substitute Chemical Program. The Criteria and Evaluation Division is responsible for the overall Program coordination and management, the performance of the Program reviews, the liaison efforts, and special study efforts in the areas of economics and some specialized areas of toxicology and chemistry.

The Registration Division is assisting us in supplying data that were submitted by the registrants for a pesticide's registration to assist in the review process. We're also returning Program reviews to the Registration Division, even before they go to final printing, to aid them in their re-registration process.

The Technical Services Division of the Office of Pesticide Programs is supplying monitoring data on all the pesticides that are being environmentally monitored under their programs. Not all of the potential substitute pesticides are being monitored, but those that are being monitored are being reported on. The

Operations Division has the responsibility of pesticide accident reports and is supplying us with accident data they've collected on substitute pesticides under review.

We started working with the EPA regions about 4 months ago. Five of 10 regions are actively participating in a program. The regions are looking at state and local pesticide use recommendations, in particular if the states recommend the use of certain problematic pesticides that have not been cancelled or suspended yet or if they recommend the use of certain substitutes. We also go directly to the states for efficacy data obtained by the state extension services, since a great multitude of these data have not been published. The states are also requested to identify critical uses of either substitutes or problematic pesticides.

EPA's Office of Research and Development performs research management at the headquarters office in Washington, D.C. Dr. John Buckley has been our prime contact and has done an excellent job over the past 15 months in implementing the Program throughout the various Office of Research and Development laboratories. The Health Effects Research Laboratory at Research Triangle Park performs the three functions of toxicological research, methods development, and pesticide chemicals repository. The Environmental Research Laboratories in Corvallis, Oregon; Duluth, Minnesota; Gulf Breeze, Florida; and Athens, Georgia are also assisting in the Substitute Chemical Program.

The major Program accomplishments during FY-75 are summarized below.

- Initiated over 40 Program reviews of potential substitute chemicals.
- Published Program reviews of parathion, methyl parathion, malathion, bromacil, captan, and aldicarb.
- Maintained contact with other agencies, industry, and academia through conferences, individual meetings, and reports.

- Conducted research and special study support programs both within EPA laboratories and through grants and contracts.

Over 40 Program reviews of potential substitute chemicals have been initiated, and 6 of these have been published. You'll be getting information, if you don't already have it, on how you can obtain copies of them. Contact has been maintained with other Governmental agencies, industry, and academia and many research and special study efforts have been conducted. Interagency agreements have been initiated with USDA, USDI, and the National Center for Toxicological Research to further support the Program.

There is not one sole purpose for the Program. A lot of spinoff benefits have been obtained from the project now that it is fully operational and getting more and more visibility throughout the Agency. In addition to the major accomplishments we just mentioned, I'd like to talk about some of the additional Agency benefits -- spinoffs, you might say, of the Program. They are as follows:

- Cancellation decisions and litigation support
- Safety screening for pesticide chemicals
- Pesticide re-registrations
- Scientific data base development
- Environmental impact statements

The first one, cancellation decisions and litigation support, indicates that EPA's position to cancel or suspend the pesticide registration under FIFRA, as amended, can oftentimes be supported by proving that there are safe and efficacious pesticides available to replace a suspect chemical on a use-by-use basis. Results of the Substitute Chemical Program can be of great assistance in the litigation area.

The second spinoff is safety screening. The screening techniques being developed to rapidly evaluate selected parameters of potential substitute chemicals will greatly assist both the registrants and the Office of Pesticide Programs' Registration Division. These techniques will be made publicly available, and it is highly conceivable that they may eventually reduce the expense to all parties of developing and registering a pesticide product.

Pesticide re-registration is another benefit. The data bases derived by the review process are forwarded to the pesticide's individual product manager in the Office of Pesticide Programs' Registration Division, along with our recommendations with respect to 5-year re-registration of that pesticide. Data deficiencies applicable to the re-registration process are also highlighted to the product manager.

Next is the scientific data base improvement at EPA. Through the high degree of registrant cooperation experienced during the first year of the Program, many yet unpublished papers have been voluntarily supplied by registrants to aid in the review process. These papers have been primarily the result of the registrants performing defensive research not required by the normal pesticide registration process.

Finally, we benefit from the Program in environmental impact statement preparation. Recently the Agency was required to publish an environmental impact statement to support all major EPA regulatory decisions. The results of this Program will provide a critical input to this effort, since environmental impact statements must consider all feasible alternatives.

The review process (Subplan A) is broken into two steps shown below.

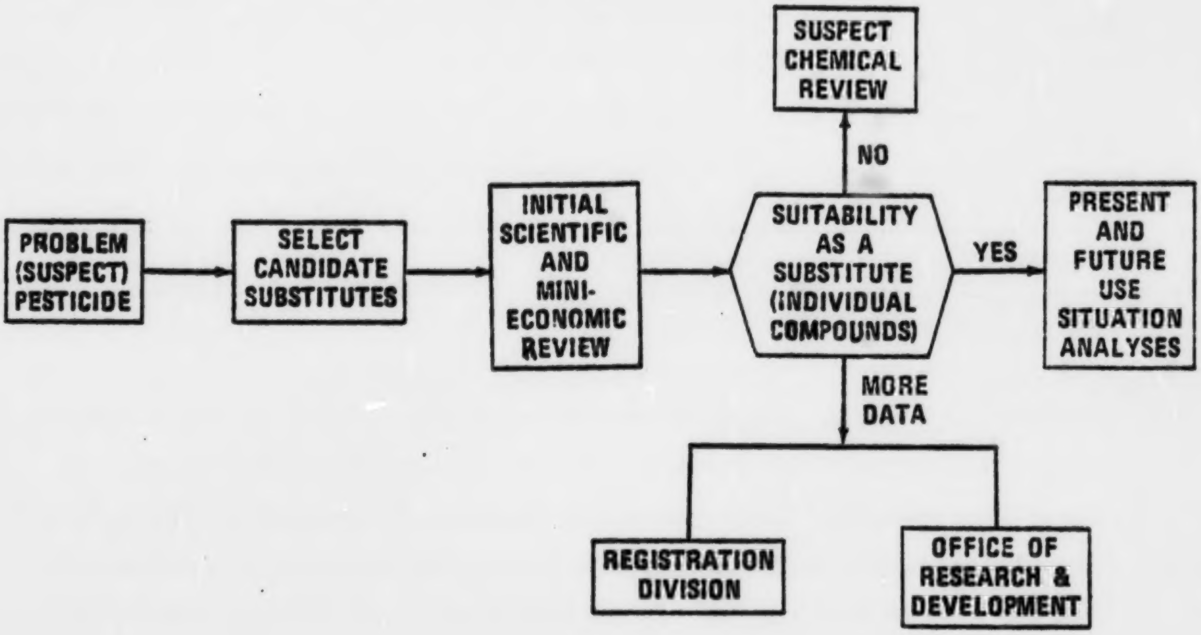
- Step 1: Conduct Initial Scientific and Mini-Economic Reviews of potential substitute chemicals to determine their individual suitability as substitutes.
- Step 2: Analyzing specific problematic pesticide use situations to determine that the user will have safe and available substitute pesticide products.

The first step, the Initial Scientific and Mini-Economic Review , is performed on individual pesticides which have potential as substitutes. Step 2, analysis of specific problematic pesticide use situations, concentrates on pest crop or other use situations that were or are now controlled by a problematic or suspect chemical. This second step is problem-oriented, since, in many cases, more than one substitute is required to control a particular problematic pest use situation.

Figure 1 shows the sequence of events of a Substitute Chemical Program evaluation of potential substitutes to replace selected problematic pesticide uses. This sequence concentrates solely on the Substitute Chemical Program analysis and does not indicate benefits to other EPA activities, such as litigation or reregistration.

Figure 1

The Review Process


PROBLEM (SUSPECT) PESTICIDE
SELECT CANDIDATE SUBSTITUTES
INITIAL SCIENTIFIC AND MINI-ECONOMIC REVIEW
SUITABILITY AS A SUBSTITUTE (INDIVIDUAL COMPOUNDS)
NO
SUSPECT CHEMICAL REVIEW
YES
PRESENT AND FUTURE USE SITUATION ANALYSES
MORE DATA
REGISTRATION DIVISION
OFFICE OF RESEARCH & DEVELOPMENT

The first step is to look at the various use patterns that require substitutes after problem suspect chemical uses have been identified. We have been asked many times to describe just how candidates are selected for the substitute review process. Figure 2 indicates the matrix by which registered compounds with use registrations corresponding to those of the problematic or suspect chemicals are identified.

Figure 2

Use Matrix

	REGISTERED USES OF CHLORDANE/HEPTACHLOR REQUIRING SUBSTITUTES			
ALL REGISTERED SUBSTITUTES	CORN ROOTWORMS ON CORN	WIREWORMS ON CORN	CUTWORMS ON CORN	ANTS ON LAWN & TURF
BUX	●			
CARBOFURAN	●	●		
DASANIT	●			
DYFONATE	●	●		
DIAZINON	●		●	●

This is the starting point in selection of candidates. Across the top of Figure 2 (which is a portion of the chlordane/heptachlor substitute use matrix) are some sample "problematic" uses registered to chlordane and heptachlor. The various substitutes that are registered for these uses are examined and then corresponding use patterns are identified. Following this step candidates are selected for substitute review on the basis of two factors: Compounds that have several corresponding uses and compounds that are perhaps the only substitutes available for a particular problematic use are placed high on the list for review.

Once the selections have been made from the use matrix, state extension service recommendations are examined. Recently, in cooperation with USDA, all 50 states were surveyed with respect to recommended chlordane and heptachlor uses and any recommended substitutes that the states or local agents might have for similar use patterns. In addition, an assessment of a supply demand situation was made using the Criteria and Evaluation Division's Economics Analysis Branch. If a pesticide or potential substitute is high on our priority review list and farmers just can't seem to get enough of it, that would certainly be a factor to consider in the analysis when we are looking at its increased use. Once all compounds are selected for review, the Initial Scientific and Mini-Economic Reviews are initiated.

This review examines the current scientific and economic data bases within a fixed amount of resource commitment; thus, the name, initial. Those of you who attended last year's Denver conference will probably recall Dr. Axelrod's slide of all of the mountains. Just mountaintops of the data are contained in an Initial Scientific and Mini-Economic Review.

It is difficult to determine when you should stop and print one of these reviews because as more and more data bases turn up, the scientists have to make a judgment as to what depth of study is needed. When they feel sufficient data are available to make the type of analyses that is required under the Program, the review is published. A full treatise on the compound could be prepared which could end up being several thousand pages, but this would be inefficient with respect to the goals of the Program.

Various disciplines are contained within the review, and these will be discussed in detail a little later. After the completion of an initial review, a position document, containing only opinions, is drafted by the Criteria and Evaluation Division. The position document recommends one of three options (see Figure 1). The first option, which we have not yet run into, is a situation in which some new evidence is uncovered on an existing registered compound that perhaps is strong enough on the potentially hazardous side to suggest this compound should go into a suspect chemical review for possible litigation action. As I said, so far we have not come to that point in the first year, but it probably will happen sooner or later.

Second, we might find that we need more data, especially on some older substitute compounds that were registered 15 to 20 years ago when the registration requirements weren't as extensive as they are now. We divide those data needs into two areas: We will ask the Registration Division to get the data for us in the reregistration process, if it falls under the umbrella of the new Guidelines. If it doesn't fall under the Guidelines or is not specific enough to ask the registrant for (i.e., data on two or three compounds being applied together), we request the Office of Research and Development through ORD headquarters to obtain these data.

Up to this point we have been dealing just with individual compounds. Now we'll be stacking the compounds up here (prior to the last box in Figure 1), the ones that come through the first part as suitable substitutes. Then various problematic use situations are examined in conjunction with the various substitutes that are available to be applied to that use pattern.

At this time I'll briefly go over the various components of the Initial Scientific and Mini-Economic Review listed below. These reviews are being produced, averaging about 200 pages.

- Pharmacology and Toxicology: Acute, subacute, and chronic toxicity to laboratory and domestic animals, metabolism, effects on reproduction, teratogenic effects, behavioral effects, mutagenic and oncogenic effects, effects on humans
- Fate and Significance in the Environment: Effects on aquatic species, wildlife, and beneficial insects; residues in soil, water, and air; bioaccumulation biomagnification; environmental transport mechanisms
- Registered Uses: Registered uses, recommended dosages, and limitations of use

- Economics: Broad use patterns by region and crop; production and domestic supply; efficacy and cost effectiveness
- Summary: Summary of each section of the report and limitations in available scientific data
- Chemistry: Synthesis and production technology, physical properties, analytical methods, composition and formulation, chemical properties, degradation and decomposition processes, residues, ADI, tolerances

The final step in evaluating the suitability of substitutes for particular pest control situations is substitute use situation analysis. When multiple substitute compounds may be considered for a particular use, you must go back to some of the parameters you looked at originally and evaluate them from a different standpoint. The outline of substitute use situation analysis is as follows:

- State and local pesticide use recommendations
- Substitute availability evaluation
- Matrix of corresponding uses
- Present and future efficacy (economic benefits)
- Present and future health and environmental effects
- Market choice

The use situation analysis evaluates all problematic uses of the suspect chemical with respect to the safety and efficacy of substitutes considered suitable by the Step 1 or Initial Scientific and Mini-Economic Review. It replaces the Biosphere and Socioeconomic Review, which was discussed in detail last year in Denver. The original approach was to get into Step 2 and get into a lot of detail, a very in-depth analysis on particular substitutes on an individual basis, but we're finding that that is not practical, and we have to consider solutions to the problematic use here rather than the pesticide.

This analysis can range from a simple one-to-one comparison of substitute and suspect to more comprehensive analysis of several substitutes that may be required to control a pest complex formerly controlled by a single suspect chemical. An example of this is the corn soil insect complex with respect to chlordane and heptachlor where combinations of two or more suitable substitutes must be considered for certain pest infestations.

A use situation analysis is practically oriented, and it examines what the user would probably employ if a problematic pesticide were not available due to an adverse EPA action. It examines factors such as what pesticides would be recommended by the state, county, or other informed source, and it estimates the present and future availability of these recommended pesticides. Once probable pest control strategies have been estimated, these new use patterns will be examined with respect to human safety, environmental, and efficacy factors. Both present and anticipated 5-year increases in use patterns of the substitutes are examined.

We are attempting here to eliminate what has sometimes been referred to as the domino effect; that is, cancelling a compound for unreasonable adverse effects after it came into increased use following the cancellation of a previous compound. Where possible, enough pest control strategies will be examined to provide the user with a market choice of products for a particular use pattern. We're not just going to look at enough substitutes to cover the problem once over. It would be advantageous if the user had several choices of substitutes for particular problematic use situations. However, if many substitutes are identified for a use, we do not look at all because it would be a poor utilization of resources. The use situation analysis should prove that there are at least enough products available to cover a particular problem area.

STATUS OF SUBSTITUTE CHEMICAL REVIEWS

Linda McIntyre*

Forty reviews of different pesticide chemicals have been initiated to date under the Substitute Chemical Program. These reviews are in various stages of the review process with six completed and publicly available. I will be discussing the current status of these Phase I Initial Scientific and Mini-Economic Reviews this morning. The first Phase II analysis, which Mr. Olsen described earlier, is just getting underway and there is not any significant progress to report yet. Initial results are expected in a few months.

Figure 1 shows the major steps or milestones of the Phase I review process. Once a chemical is selected for review as a potential substitute for specific uses of a problematic pesticide, based on corresponding use registrations and state recommendations, the registrant is notified that his chemical is under review. At this time he is asked to provide supplemental data which can best be supplied at the corporate or agency level and he is informed as to when he can be expecting to receive a draft report of the review for comment.

The next step is the preparation of the draft report. This review report is a compilation of available scientific and economic data and is conducted on a level-of-effort basis. Contractors and Criteria and Evaluation Division scientists are given detailed outlines and resource estimates for the various sections of the review to guide their work. Thus, the name "initial review" is appropriate and implies that this is not expected to be a comprehensive and all-inclusive report.

Contractor support has been utilized for the preparation of most reviews to date. Although the Criteria and Evaluation Division was authorized positions to

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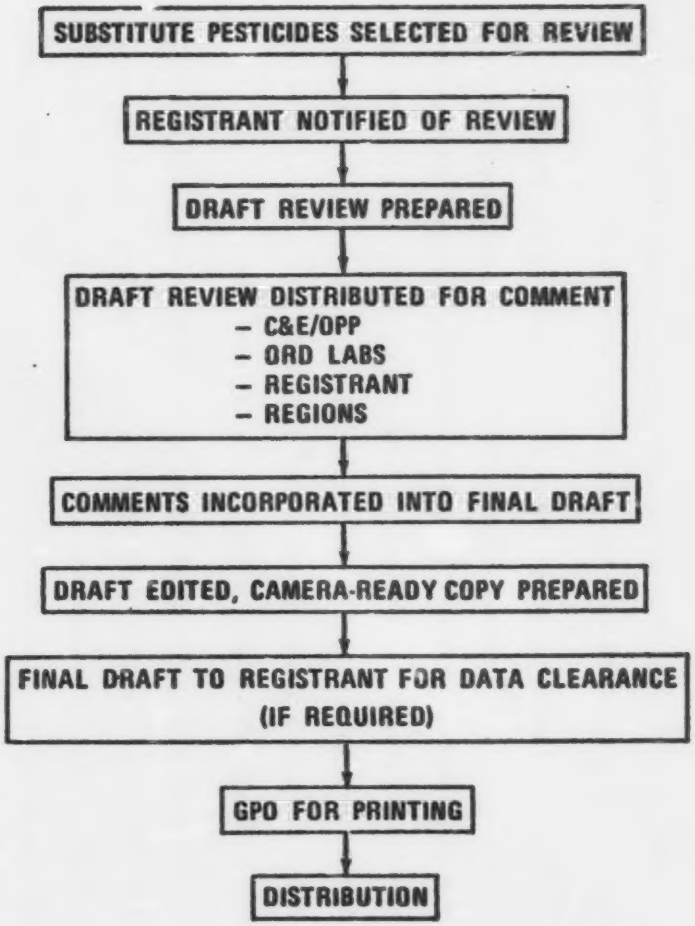
*Criteria and Evaluation Division, EPA

Figure 1

Major Milestones of the Phase I Review Process


SUBSTITUTE PESTICIDES SELECTED FOR REVIEW
REGISTRANT NOTIFIED OF REVIEW
DRAFT REVIEW PREPARED
DRAFT REVIEW DISTRIBUTED FOR COMMENT
– C&E/OPP
– ORD LABS
– REGISTRANT
– REGIONS
COMMENTS INCORPORATED INTO FINAL DRAFT
DRAFT EDITED, CAMERA-READY COPY PREPARED
FINAL DRAFT TO REGISTRANT FOR DATA CLEARANCE (IF REQUIRED)
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do this work, inherent time lags in hiring qualified scientists in the Government necessitated contract support when the Program was first initiated, so that some progress could be shown within reasonable time frames. Currently Midwest Research Institute, Arthur D. Little, and Tracor-Jitco are providing this contractor support. Although we have now hired our scientific staff, we will be continuing to use contractors for the more mechanical tasks of literature searching and abstracting so that our personnel may be more heavily utilized in the problem analysis tasks of the Phase II Use Situation Analyses.

Draft reports are reviewed by the Criteria and Evaluation Division scientific staff and further guidance given to the contractors as far as additions, deletions, or changes in interpretation to be made. Concurrently, these draft reports are forwarded to the registrants for review, and nonproprietary sections of the report are also sent to the EPA regions and to the Office of Research and Development labs involved with pesticide research for their review and comment.

Any additional material and comments we receive from the registrant or EPA labs are incorporated into the final draft as appropriate. Discussions are also held during this time with individual registrants to answer specific questions they might have on the review or the Program itself.

The technically completed draft is edited, and camera-ready copy is prepared for printing. A final copy is sent to the registrant for clearance of any company-supplied data which have not been previously released. Cleared copies are then sent to the Government Printing Office (GPO) for printing and are publicly distributed. This, briefly, describes the review process.

The following tables illustrate the status of the reviews which have been initiated to data. It should be noted, however, that these lists are not intended to be all-inclusive. In most cases many more substitutes were identified, but due to resource constraints, could not be reviewed. One must remember that the purpose of the Program is not to review all substitutes but to review only enough substitutes to give a reasonable assurance that the problem created by a cancellation or suspension action will be minimal.

At the initiation of the Program, substitute pesticide lists were not readily available. Many registrants felt that being on any EPA list of pesticides under review placed them in a detrimental position. However, now that the reports are becoming available and the purpose and intent of the Program is more widely understood, these lists have become public knowledge. In fact, the June 9 issue of Chemical and Engineering News published a list of most of the pesticides being studied under the Program.

Table 1 shows the 14 insecticides selected for review as potential substitutes for cancelled uses of DDT, based on corresponding use registrations and the use patterns that had developed since the cancellation. Reports of aldicarb, malathion, methyl parathion, and parathion have been printed and are publicly available. The crotoxyphos review is currently being printed by GPO and should be available within the next month.

Table 1: Substitute Chemical Program Status of Reviews
July 1975

Substitutes for DDT	Registrant Notified	Draft Review	Distributed for Comment	Final Draft	Edit	Registrant for Clearance	GPO for Printing	Distribute
Aldicarb	•	•	•	•	•	•	•	•
Azodrin	•	•	•	•				
Chlorpyrifos	•	•	•					
Crotoxyphos	•	•	•	•	•	•	•	
Demeton	•	•	•	•				
Diazinon	•	•	•					
Dimethoate	•	•	•	•				
Fenthion	•	•	•					
Guthion	•	•	•	•				
Malathion	•	•	•	•	•	•	•	
Methomyl	•	•	•					
Methyl parathion	•	•	•	•	•	•	•	•
Parathion	•	•	•	•	•	•	•	•
Phorate	•	•	•	•				

The reviews of Azodrin, demeton, dimethoate, guthion, and phorate have been completed from a technical standpoint. These reports are currently being edited prior to submission to the registrants for their final review and subsequent printing. Draft reports on chlorpyrifos, Diazinon, fenthion, and methomyl have been completed and distributed for review by registrants.

Table 2 shows the status of the eight herbicides which have been selected for review as potential substitutes for cancelled uses of 2,4,5-T. The bromacil report has been printed and is available. Initial Scientific and Mini-Economic Reviews of cacodylic acid and MSMA/DSMA have been edited and will be sent to the registrants for final clearance shortly. The monuron review is technically completed, and it is currently being edited. Drafts of the dicamba, DNBP, and trifluralin reports have been sent to registrants for review and we are currently awaiting their response. The simazine report has been initiated and we are expecting a draft to be completed in early September.

Table 2: Substitute Chemical Program Status of Reviews
July 1975

Substitutes for 2,4,5-T	Registrant Notified	Draft Review	Distributed for Comment	Final Draft	Edit	Registrant for Clearance	GPO for Printing	Distribute
Bromacil	•	•	•	•	•	•	•	•
Cacodylic acid	•	•	•	•	•			
Dicamba	•	•	•					
DNBP	•	•	•					
Monuron	•	•	•	•				
MSMA/DSMA	•	•	•	•	•			
Simazine	•							
Trifluralin	•	•	•					

Three fungicides (Table 3) are being reviewed as potential substitutes for the EBDC fungicides which are under internal EPA suspect chemical review. The captan review has been completed and the report distributed. The review of

PCNB has been edited and will be sent to the registrant shortly for final review and clearance. The draft on folpet has been sent out for review, and we are currently awaiting comments from the registrants and Office of Research and Development labs.

Table 3: Substitute Chemical Program Status of Reviews
July 1975

Substitutes for EBDC Fungicides	Registrant Notified	Draft Review	Distributed for Comment	Final Draft	Edit	Registrant for Clearance	GPO for Printing	Distribute
Captan	•	•	•	•	•	•	•	•
Folpet	•	•	•					
PCNB	•	•	•	•	•			

Most recently, 15 potential substitutes have been identified for problematic uses of aldrin, dieldrin, chlordane, and heptachlor (Table 4). All registrants have been notified that their compounds are under review as part of the Substitute Chemical Program. The carbofuran report has been reviewed by the manufacturer, and the final report is now ready for editing. Draft reports on the herbicide Dacthal and the insecticides disulfoton and Dyfonate have been completed and sent out for comment. We are expecting drafts of ethion and Aspon to be ready shortly.

Most of the pesticides which have been selected for review to date have broad use patterns and multiple registrations. Although they are initially being reviewed as potential substitutes for a specific problematic compound, it is conceivable that they could later also be identified as potential substitutes for other chemicals. Table 5 shows, for example, the overlap of multiple registrations which exist for the insecticides currently under review.

When a pesticide is designated as a potential substitute for a problematic chemical at a later date (for example, parathion, which was initially reviewed as a DDT substitute, is also a substitute for aldrin, chlordane, and heptachlor uses), the review, which covers all uses, needs only to be updated to include data which have been made available subsequent to the original publication. The review can then be used as the basis for another position document, evaluating its suitability to substitute for the new problem chemicals. Additional data deficiencies which might be unique to this new chemical and subject use patterns will be identified and procedures initiated for filling them. This practice of having all uses of the substitute examined in the Initial Scientific and Mini-Economic Review allows a more efficient use of resources devoted to the Substitute Chemical Program.

Table 4: Substitute Chemical Program Status of Reviews
July 1975

Substitutes for Aldrin, Dieldrin, Chlordane, Heptachlor	Registrant Notified	Review	Distributed for Comment	Final Draft	Edit	Registrant for Clearance	GPO for Printing	Distribute
Acephate	•							
Aspon	•							
Bux	•							
Carbofuran	•	•	•	•				
Counter	•							
Dacthal	•	•	•					
Dasanit	•							
Disulfoton	•	•	•					
Dyfonate	•	•	•					
Ethion	•							
Ethoprop	•							
Methoxychlor	•							
Propoxur	•							
Siduron	•							
Trichlorfon	•							

Questions have been raised by several parties regarding the availability of the reports and how to acquire them. Demand has been much greater than we originally anticipated for these reviews. Thus, our supplies of the first ones printed are currently exhausted and they are not available for distribution today. However, we are having these earlier reports reprinted, and a greater number of copies of the future reports will be printed. Limited numbers of reports will be available from the EPA Form and Report Center in Durham, North Carolina. After these are exhausted, reviews can be purchased in either microfiche or printed copy from the National Technical Information Service (NTIS) in Springfield, Virginia.

Table 5: Substitute Chemical Program

Insecticides Under Review	Substitute For				
	DDT	Aldrin	Dieldrin	Chlordane	Heptachlor
Acephate	●		●	●	
Aldicarb	●				
Aspon	●	●	●	●	
Azodrin	●				
Bux		●		●	●
Carbofuran	●	●		●	●
Chlorpyrifos	●	●		●	●
Counter		●		●	●
Crotoxyphos	●				
Dasanit	●	●		●	●
Demeton	●				
Diazinon	●	●		●	●
Dimethoate	●				
Disulfoton	●	●		●	●
Dyfonate	●	●		●	●
Ethion	●	●	●	●	
Ethoprop		●		●	●
Fenthion	●				
Guthion	●				
Malathion	●				
Methomyl	●				
Methoxychlor	●		●	●	
Methyl parathion	●				
Parathion	●	●		●	●
Phorate	●	●		●	●
Propoxur	●	●	●	●	●
Trichlorfon	●	●		●	●

DR. ROESSLER: Thank you, Linda. Just a friendly little dig -- in one phrase of your talk, Linda, you said something about changes in data, and I presume the people in the audience caught that. We really can never change data. We may ask for more data, or we may ask for a different evaluation of the data, or we may interpret it in a different light, but, of course, we never look for a change in data, because data is data.

REGIONAL PARTICIPATION

Richard Walka*

It's a pleasure to meet with you this morning to discuss a relatively new aspect of the Substitute Chemical Program, that of regional input. The value and importance of such input into the Program is exemplified in New York State alone by the fact that there are over 6.4 million acres of farmland supporting over 30 varieties of major crops. This obviously creates a need to use efficacious pesticides in controlling specific insect and fungal diseases associated with these crops.

Another important consideration in the Program's chemical review process is the fact that in New Jersey alone there are over 200 producers of agricultural chemical pesticides, and these producers are supplying a very large cross-section of the country. In light of the number of pesticide manufacturers in Region II, the economic impact of cancellation or suspension orders must be fully evaluated in detail.

The Criteria and Evaluation Division has requested that each participating region supply specific information on local pesticide use patterns and economics that is not always available at the headquarters level. This is what makes regional input most desirable.

The technical data required from the regions are then incorporated into the review process, which will ultimately determine the suitability of chemicals for pesticides that are cancelled, suspended, in litigation, or under internal review for unreasonable adverse effects against man or the environment.

In January 1975, a formal letter was sent out to the regional pesticide branch chiefs inviting their participation in the Program. Recognizing the availability of the resources and the capabilities at the local level through the extension services and the agricultural experimental stations, the Criteria and Evaluation Division requested us to supply technical pesticide data according to the following directives.

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*EPA Region II

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We were to determine the availability of selected pesticides in a geographic location by contacting local suppliers and users; collect and reduce data on state-recommended pesticides for specific uses; provide inputs on agricultural practices in an area, particularly those that may be locally unique; and identify any local problems concerning the efficacy of these pesticides.

In addition, the region was requested to prepare specific comments on the draft copies of Production and Mini-Economic Use Reviews on these chemical substitutes.

Since the time that a regional input was originally addressed, many of the regions have responded favorably; however, it is now apparent that the tasks performed by each region must be tailored to the specific needs in their locale.

Some examples of the different approaches undertaken by regions in obtaining the desired information include the development and maintenance of grants with universities, in-house studies, and the hiring of new personnel at the regional level to deal with the increased workload.

The Criteria and Evaluation Division in cooperation with the Office of Research and Development has agreed to the transfer of funds to cover any manpower/hour expenditures that the region may incur in obtaining these technical data. In our own region we have chosen the grant route, being particularly interested in negotiating grants with either the agricultural extension service or the experimental stations with the states in our region. It is here that the expertise concerning local agricultural problems is available from both researchers and extension specialists who have a long-running experience with the pesticides and are most familiar with the pest crop problems in the area. This is obviously the best means of obtaining firsthand information which will be considered in the review process for determining the suitability of alternative chemicals.

Under specific provisions of our grant to Cornell University, the College of Agricultural and Life Sciences was funded to gather technical and economic data pertinent to the alternative chemicals under review. I would like to take this opportunity to review some of the outputs that were required from Cornell University under the grant.

The introductory statement of the grant basically outlines what we want the extension service to do. The grant requires the funding of a "use analysis investigator" to obtain the technical and economic data requested by the Criteria and Evaluation Division. Dr. Dewey of Cornell University will be working along with the investigator in gathering most of this information, according to the objectives that I stated previously.

Output paragraph number two states that the use analysis investigator will be responsible for developing a mechanism which will be used in gathering the information. We are presently in the process of working this out with Dr. Dewey. I'll have a little more information on that later.

Paragraph three reiterates the specific substitute chemical directives which will be incorporated into the review. From a list of directives that was sent to our region, we had to tailor a grant which would allow us to analyze the local needs in New York State. Specifically, we chose to review the availability and cost of each chemical substitute to the user within specific locations in the state, probably on a county-wide basis; to review farmer and extension specialist attitudes toward the effectiveness of each substitute; and also to indicate any specific problems that they have in the efficacy of these pesticides.

Regional pest crop use patterns will be studied as far back as about 1970, and we will also have a discussion of the total number of uses for each substitute as is recommended in New York State by Cornell University in their "Red Book" and compare those to the registered uses in the EPA compendium, which are often conflicting in nature.

Explanations as to why "Cornell Recommends," which is their publication, differs from the pesticide registrations in the EPA compendium will be discussed in detail and included in each report.

Paragraph six states that the investigator will be responsible for identifying and reviewing critical uses of chlordane and heptachlor on minor crops in New York State. The critical uses will be those for which few or no other pesticides are registered or recommended.

The last output paragraph, which may be one of the more important ones, concerns the ongoing research at the extension service. The investigator will be responsible for acquiring information regarding ongoing research at the extension service, a lot of which is never published or made known to the public. This information may be in the form of reports or data that have been unpublished or used solely at the extension service.

Program management and review specifies that the grant will be monitored on behalf of EPA Region II by the project officer and performance under the grant will be monitored on behalf of the Cooperative Service by Dr. Dewey, who is the pesticide chemical coordinator. Draft reports of the scheduled substitute chemical reviews will be submitted to the regional office at least 30 days prior to the date assigned to it under final draft, so that regional and headquarters comments can be incorporated into these reports.

We are looking forward to negotiating and developing similar special studies in fiscal years 1976 and 1977 with other states in our region; however, we feel that a preliminary look into the necessity of such studies must be conducted to evaluate their importance and value in the Substitute Chemical Program. Again, it is important to remember that the chemical reviews require many current data bases and disciplines including toxicology, pharmacology, chemistry, environmental impact, and economic analysis.

Although at this time regional input is still at a beginning stage, it is most beneficial, since the acquired information will help fill in existing data deficiencies. The research and special studies being conducted through the Substitute Chemical Program can only aid in better understanding the movement and ultimate fate of these pesticides in our environment and better enable us to regulate their use in the future.

DR. ZWEIG: Could you tell us the size of the grant?

MR. WALKA: The size of the grant was $10,000 to the Agricultural Extension Service, College of Agricultural and Life Sciences.

REGISTRANT OVERVIEW

Dr. Richard C. Back*

I have a unique position in that I'd like to speak as an individual, devoid of company and industry affiliations, but that's impossible. I am in a unique position, I think, in talking about DDT substitutes. We have one of the best in the world. It's called Sevin Carbaryl Insecticide. It controls worms, and that's what DDT does, but it has not been investigated under the Substitute Chemical Program. Instead, they picked another one of our products called aldicarb, which I do not think is a DDT substitute.

This is called the Substitute Chemical Program over the objections of industry and most of the registrants, who wanted to call it the Alternate Chemical Program. It's really a chemical study program, not a substitute chemical program in essence, and I feel that EPA is tackling an admirable job in trying to develop for the public an extensive fact sheet on each pesticide. They're doing a good job of it, and they're getting a lot of help.

But it's really not, or should not be, a chemical study program because there are a great many chemicals that are not pesticides. It should be a pesticide study program. And then, if we go a little bit further, one of the best alternatives to DDT is the fly swatter and the window screen. And therefore I think it should be considered a pest control study program. After all, we're all interested in integrated control. It's a brand new thing. We just discovered it a year or two ago, but we've all been practicing it our whole lives. Everything we do is integrated.

Coming specifically to this Program, I have some general comments and I have some more specific ones that are directed to the aldicarb review in which I was involved. First, I think EPA should notify the registrant before they let a contract anywhere and should give the registrant an opportunity to provide the data he wants to provide so that EPA can make it available to the contractor, and the contractor will thereby be highly enlightened.

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*Union Carbide Corporation, Washington D.C.

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I think that the contract should be let to organizations that know something about pesticides basically to begin with and, hopefully, specifically something about the products under consideration. I think these two points will save the United States, you and me as taxpayers, time and money. That's why I suggest it. I think that the review should mention reasons for the review in the introduction. As of now, the reviews are devoid of the reasons they were undertaken. For instance, in the case of aldicarb, the introduction should state that this study was done to consider the product as a substitute for DDT. If you go back and consider it as a substitute for something else later on, you may have to revise the introduction, but the purpose should be stated at the onset.

Data on the production volume of any product are sensitive disclosures to any manufacturer who is a sole maker and patent holder of that product. These production data are provided to EPA in confidence under Section 7 — not only this year's production, but our guess as to what we're going to do next year. I do not feel that there is any reason for putting production data in these reports. The production data that are in the reports undoubtedly are innocuous, or they wouldn't be there, but I don't think that this is of any value in assessing the alternative worth of a product. We may find ourselves recommending things as alternates that aren't even made anymore if we don't look out.

The information that is provided in these reports on practical use and the benefits of the product is strictly subordinated to what I now understand very clearly is the prime EPA charge, "to protect human health and the environment." The original intent to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which was to protect the consumer against ineffective products, has been lost. I'd like to see much more attention given to uses and benefits on a page-by-page basis. If you want to be so blunt as to put it that way, let's have 50 pages on what the product is good for because that is why people buy it and 50 pages on potential hazards and risks.

The Mini-Economic Review, I feel, needs improvement. I've stated my case before to Ken Olsen. He knows about it. But when we talk about yield in dollars per acre of the crop after treatment or in competition with alternate products or competition with no product, you see X dollars per acre gain or loss. In some cases there is a loss because the cost of pesticide applied is deducted, and if there are no pests present, obviously, you're not going to get any difference in yield between treated and control plots. But the important thing here is that if a company has run several hundred comparison plots, comparing yield and getting dollar value out of it, what it wants emphasized is the average yield change due to pesticide use, not the highest number and the lowest number as have been reported in these reviews.

For instance, if we lose $50 an acre in one case and gain $300 an acre in the other case, that's very great, but it won't convince a farmer nearly as well that he's got something worth using if he knows that his average likely increase is going to be $200 per acre. I understand that these reports are intended to have interpretations and opinions on the data omitted. Nevertheless, these reports do cite what somebody thinks are deficiencies in the data. I would move to have the deficiencies taken out of these reports. They are opinions. And perhaps you'll see things that the Guidelines, still in draft form, called for, and yet they're not available. But I think these things should be put in the position statement.

And I believe that the disclosure of the EPA position document to the registrant is highly desirable. I would like to stop right here -- and disclose it in confidence, if you wish. That's all right. We have five or six of these reports here in published form, but I disagree that they're publicly available. But how many position documents have been written on the basis of these reports? Will someone from EPA please answer?

MR. OLSEN: One for each.

DR. BACK: I hope that you will consider making them available to the people whose products they are, the registrants.

Now in the review situation of aldicarb, commonly known by the trade name Temik aldicarb pesticide, Union Carbide and the Criteria and Evaluation Division have been in contact on this over a 9-month period, and I think it's very much to

Ken Olsen's credit and the credit of the rest of the people who work with him that the report has been published. I have found in three official meetings betwen our company and EPA that they are exactly what they advertise, agreeable and cooperative. I've got no complaints there.

I disagree with the basic premise that aldicarb is a substitute for DDT, and I know Ken disagrees with me. However, I want to point out to those who are not familiar with both compounds a few of the differences. Aldicarb is marketed only as a granular product. DDT was used mainly as a wettable powder, dust, emulsion, concentrate, or solution. Aldicarb is placed in the soil. DDT is usually placed on the foliage. Aldicarb is applied once, maybe twice a season; DDT, more frequently. Aldicarb is systemic on plants; DDT is not. Aldicarb is a reversible cholinesterase inhibitor; DDT is not. Aldicarb biodegrades; DDT bioaccumulates. Aldicarb controls nematodes, mites, and insects; DDT does not control all of these. Aldicarb does not kill lepidopterous larvae and DDT does.

Most professional entomologists and nematologists, in my opinion, do not consider aldicarb an alternate for DDT because the majority of the uses and characteristics of the two chemicals are very different. Perhaps one reason the first draft that we saw of this review was so poor was because the contractor was only given 20 man-days to review what we had spent 7 years developing and bringing to market.

The original work, coverage on the subject of toxicology in general, was taken from petitions which had subsequently been withdrawn. This situation was corrected in the review. The crop residue information is not treated extensively enough. Plenty of attention is given to residues in the environment, soil, and water, etc., but the bases for the established tolerances are not considered extensively in the report.

There's very poor treatment in the review text of common versus the trade names, and I realize the problem that EPA or any Government agency has in using a trade name in their publications. Nevertheless, when we're applying 10, 20, or 30 pounds of a formulation per acre, and that's the way it went down, I think that's the way it should be put in the table. There's no way of getting around it.

Union Carbide Corporation is the patent holder on this product. It is the sole maker of this product worldwide, and very regrettably, I feel, this report does not credit Union Carbide with having brought this product to market. Overall, I think that the idea of writing reviews is worthwhile, but I don't think that the reviews in themselves are going to help substitute for a lost product like DDT or any of the others that we'll probably hear more about today. I think that the way these products are going to be substituted is by an old-fashioned system called American free enterprise.

MR. OLSEN: Thanks for your comments. I think we ought to answer a few of them. I should make the comment, first of all, that aldicarb was one of the first four compounds that we placed in the review process, and at that time our experience was low on the learning curve. At the present time the manufacturers are notified prior to starting of any review so that we do gain that lead time. We've had that comment from Dr. Back as well as several other manufacturers during the initial course of the Program.

Now the reasons for the aldicarb review -- as I was explaining in my talk, we think of a pest-crop combination substitute, not whether it's a wettable powder versus another type of formulation when it's applied. We asked whether a chemical controls a particular pest on a particular crop. However, in many cases we are finding that three or four substitute chemicals would have to be applied in order to control the pest complex throughout the growing season.

I also feel that the production figures estimates should be in a report. By knowing how much of a compound is manufactured and how much of it's being used, we get a good feel for the potential of its use as a substitute. If we're reviewing a compound which has very low production, we wouldn't consider that as being a very viable substitute for a major product that might be pending cancellation.

I don't like the data in the report being referred to as hazard data. It's scientific data. It indicates safety, efficacy, and possible risks. These reports were really written by scientists for the scientific community and not for the general public at large. The subject matter is far too complex. I don't think there's any one individual who could digest everything in one of these reports.

I would like to read a quote from the report. It said aldicarb was identified as a registered substitute chemical for certain cancelled and suspended uses of DDT. That's right in the introduction. I don't like the phrase Substitute Chemical Program either, but it was stated as such in the Congressional mandate. But I would like to thank Dick for his comments, and if there's anyone else in the audience, any other registrant that would like to say a few words or make any other comments with respect to how the Program has been conducted, we'd be glad to hear from you.

MR. KENAGA: I'm Gene Kenaga from the Dow Chemical Company. We have two compounds in the alternate chemical review system, and certainly I would say that our company has no arguments with the concept that was originally proposed for this Program. And I would also say that EPA has been very cooperative in working with us, and I enjoy working with the personnel of EPA, so there's nothing personal involved in this whole concept of what I'm going to say. EPA has a large job to do. These reviews are very complicated and require personnel who have a wide knowledge of information in their fields.

Unfortunately, when EPA contracted these pesticide chemical reviews out to various organizations by the compound, there must have been a problem. I feel that the people who did the job initially are very poor at summarizing data. They have made many mistakes in reviewing the literature on our own compounds, and if these reviews were ever published this way, EPA would be introducing many, many errors into the literature that didn't exist there before.

Fortunately, EPA is now reviewing them carefully, and Dow is also picking up a lot of the mistakes, but this has caused the companies who are reviewing the EPA manuscripts to spend a great deal of time checking for accuracy, whereas they could have prepared their own reviews in the first place and probably done a much better job, since we are in much better command of our information and our total picture.

However, be that as it may, certain compounds were selected for review and in our case one of them was dinoseb, which is proposed as a substitute for 2,4,5-T. Again, we didn't really feel that dinoseb was a substitute for 2,4,5-T, dinoseb being a contact insecticide or herbicide and 2,4,5-T being a systemic herbicide. Our main uses for dinoseb are in soybeans, and 2,4,5-T couldn't possibly be used there, but there are some uses in common. They are both Dow compounds, and if dinoseb were an economically viable alternative to 2,4,5-T, we probably would have thought of using dinoseb as a substitute ourselves, 2,4,5-T being under attack as it is.

But in the review of the Dow compounds dinoseb and chlorpyrifos we found in the original manuscripts submitted to us by EPA that a lot of our confidential information had been looked over by the review contract companies and inserted illegally into this manuscript. We didn't think that was right, and I think EPA agrees with that. But it again makes it necessary for us to go over it and make sure that those items are excluded.

Now, in spite of the fact that we don't want confidential information published, EPA, I believe, really wants such information summarized. For example, EPA wants to use confidential information from a toxicological or manufacturing report, but not in the form of original data or the detailed figures. Nevertheless the end result of the test would still be there.

Well, Dow says it is not confidential if it is being published, and the EPA says they won't allow anybody else to use this information for registration purposes. Well, this may be true in the United States, but certainly overseas, where foreign registrant groups are using our information -- and they're handed a total package of information, such as that summarized in the reviews -- they are not going to reject the information. And so I think that "me too" registrations by other companies in other countries of the world are going to be a lot easier to come by.

I hope, though, in working with EPA we're going to come out with good summaries of the information, and, hopefully, this will be useful in the registration process. But that was not the original concept of the Program -- to facilitate registration. It was to have an alternate chemical for a rebuttable or banned pesticide. Now I feel the emphasis has been put into registration processes, which really makes it easier for EPA to review the individual products.

And you might say that that is an advantage to the company, except that we've usually already registered it and don't have to go through that process anymore. If this review was done ahead of registration, it would be more useful to us that way. And then, finally, an alternate chemical has one more big hurdle after EPA gets through with it, and that is that the company itself has to decide whether to make it or use it, and if the company isn't in a position to compete viably, economically, it won't be used anyway. The manufacturing process that EPA has in its hands to use for economic evaluation is certainly not the one that the company uses, because it only involves a few parts of the total manufacturing process and economic evaluation, and I don't think that EPA is in a position to make that decision.

But anyway, it's been a very interesting exercise, and we're surely going to continue to cooperate. But those are the comments that we see as negatives.

MR. OLSEN: I'd just like to make one comment with respect to Gene's referral to our contractors. It's very hard to find a contractor that's all knowledgeable in pesticides, and we have some contractors that are working out very well and others that are not working out so well, and through this weeding out process I think that the first draft reports that have been sent out to registrants are now of far better quality than they were perhaps a year ago. We all have a learning process to go through here, and we realize you're all going to have to bear with us.

With respect to the economic comments, I realize it's difficult to make creditable economic comparisons with respect to, say, a compound coming into increased use. This is the kind of information we will discuss with you in this second phase or use analysis type of approach that I described previously.

DR. GILLETT: Those of us in the Office of Research and Development who are reviewing the documents in your Program are faced with a difficulty that we've discussed, reviewing data that aren't there. The speakers have spoken of problems in reviewing proprietary data, but I don't think they've had to look at a report that has 67 out of 150 pages deleted and to try to make a guesstimate as to what research is needed in a particular area.

Now I'd like to have some exchange and discussion of this problem of the researcher using a document, such as the methyl parathion report, as a data base, a good summary to start his research or to refer back to for his research, trying to make sure that the document is a proper and suitable document when in fact he does not have the data in front of him to evaluate the review.

MR. OLSEN: That's a very good comment. What Jim's referring to here are the draft copies that we sent to the various Office of Research and Development labs for comment. Perhaps we've taken an overconservative approach in working with the registrants, but when we get a first draft together, we put in just about all of the data we can find Now a lot of this data, especially in the area of toxicology, is abstracted from the registration files, which, until we get final definition on the handling of proprietary data, we will keep confidential as far as the Office of Pesticide Programs is concerned. Several of the labs have made this comment, and it's starting to become more and more frequent. Perhaps we can even go out to the Environmental Research Center and discuss what these deficiencies are and not leave the material at the Research Center until we get a better readout from the Office of General Counsel.

I feel we have to adapt this conservative approach. I don't like it personally. We are looking at some alternatives for alleviating the situation somewhat. Up until today we've received clearance of all company data or registrant data that we've included in these final reports. So I think what you're referring to is just the draft reports that go out, and I would like to have some suggestions from Office of Research and Development personnel as to how we can best handle this problem. Maybe one suggestion would be to have us go to the registrant, and if you have specific information you want, perhaps we can get clearance on an individual basis for you to look at the data.

MR. HANSON: Why, if you gave permission to the contractors to look at the P&C data, can't you give it to the Office of Research and Development?

MR. OLSEN: The contractors have signed a legal document, a performance bond, which has made them liable for any data that get released. It's just like handling a DOD secret, and it's locked up in a safe. I think Tom Ferguson here from MRI could give you his data handling procedures. Data are kept under lock and key and returned back to the manufacturer. The data are not distributed, as far as the contractor is concerned. If the manufacturer or registrant would permit it, we'd be very happy to send this out to any and all laboratories.

MR. HANSON: When you say send it out, do you mean to see it?

MR. OLSEN: One of the things that we've discussed just recently with Jean Pulliam, who does all our coordination with the laboratories, is to actually have site visits and cover maybe three or four reports simultaneously and just carry the data along with us.

DR. NEWELL: Mention was made earlier by Dr. Back about the preparation and issuing of position papers. Maybe I'm a little naive, but I would appreciate an explanation about them. When were they written? What use is to be made of them? What is their availability after they have been prepared?

MR. OLSEN: The position document is strictly an opinion document. It does not contain any data. You might find attached to it a copy of the summary of the report. Opinions as to possible Agency actions with respect to a chemical are not releasable under the Freedom of Information Act. As a matter of fact, I just checked this one out yesterday. So there's nothing in the position document that contains any data or any new facts.

The position document recommends one of three actions. I think I explained a little bit about that on my slide. Perhaps I went over it a little too fast. It will either 1) justify the suitability of a compound to be a substitute, or 2) identify data gaps, which we'll either refer to the Registration Division or to the Office of Research and Development, depending on the data gap, or 3) it's conceivable that we might find out something about the potential hazard of a compound that has never been really uncovered before, and it might be such a potential hazard that we might want to place this compound under a suspect chemical review.

So consequently we do keep these things -- I hate to use the word confidential -- but, say, not within the Freedom of Information Act. Suppose we did recommend that compound X should be reviewed as a suspect chemical. The compound hasn't been reviewed thoroughly enough at this time to go out and write a notice in the Federal Register stating EPA is going to cancel or suspend or restrict the use of a compound. Therefore, in order to protect the registrant from a premature statement in the press or the Federal Register, we prefer to keep these things more or less under lock and key.

However, the Substitute Chemical Program position documents can be discussed with the individual registrant. If any of the registrants want to come in and go over that paper with us, we'd be very happy to do it.

MR. KAMIENSKI: I had the opportunity to be involved in two of these economic reviews, and I'd like to address two items. One is a comment and one is a question. The comment would go along with Dr. Back. I notice that in the two economic reviews I had reviewed there was mention of accidents that occurred from use of the two compounds. It's my understanding that these accidental injury reports are not well-documented. In fact, they appear not to be documented at all. If this is the case, they either should not be included, or if information on injuries is included, it should be mentioned that there was no follow-up on the nature of these incidents to verify if they were legitimate accidents.

My question is, where is the line drawn in the review of these toxicology papers between opinion that is contained in the paper and actual data? There have been several instances where the author's opinion has been included in the summary. I just wondered where the line is drawn as to when the data are reported versus when opinions are included in the review?

MR. OLSEN: I'll answer the accident one first, and then I'll refer the toxicology one to Dr. Dale, who is Chief of Pharmacology and Metabolic Effects Branch at the Criteria and Evaluation Division. When you, as a registrant, review a report and feel that particular accidents are unverified, we would like to know about it and investigate further. You'll probably find when the report eventually comes out, it will be documented or not included.

We get our accident data from the Operations Division, which is a separate division on the same level as Criteria and Evaluation. They get a list of compounds. We ask them for everything they have on compound X, and then we would put that in. I'm not thoroughly familiar with the types of documentation they have. This is part of the iteration of getting a report out.

DR. DALE: In these reports we try to get rid of opinions of the author in the papers who did the work. In some cases, I understand from Mr. Burnam, it has come through in our report that the author concluded that the no effect level was, say, ten parts per million, but in general we try to report only the data contained. And if such conclusions come through when the registrant reviews the papers, they should bring it to our attention that we have let them come through.

MR. BURNAM: In the case of captan I think it was mentioned that there was a similarity to known teratogens in the introduction or the first part of the teratology chapter. This is one of the reasons that there were about 14 separate teratology studies done on this compound. These were not done without reason. They were because of resemblance to the suspected or to known teratogens, and this was included in the review.

COMMENT: This is opinion.

MR. BURNAM: Well, it is our opinion that these questions should be answered in the review, and we're answering these questions that are raised with this compound. I think it's better to answer these in the review than to let them go unanswered.

DR. DATTA: On the captan paper we had to somehow or other give the historical perspective of how and why these things are done. That was what was written there. But it was not very good English-wise, so we changed those things after your comments came back. So if anybody objects to our historical perspective of this compound review, then we don't know what we should do.

DR. FLUKER: I was wondering if someone from headquarters or maybe some of the Pesticide Branch chiefs who are here could comment on Mr. Train's press conference and his announcement about a major pesticide action. (Editor's note: notice of intent to cancel chlordane/heptachlor).

COMMENT: Well, I don't think any of us here are quite prepared for that. There may be a press release or some kind of information that we can provide before the end of the conference, but at the present time I think I have to pass that one and say we'll put a hold pattern on it until I get some kind of official word that I can relay to the audience.

SUBSTITUTE CHEMICAL PROGRAM

John R. Quarles, Jr.*

It is difficult for me to come down bearing the onus of being a lawyer and to be with so many scientific people, because I shudder to think what questions you might ask me or what you might expect me to know. Obviously there are subtleties and complexities of the scientific issues that our Agency is dealing with constantly that make me very much wish that I had had the fortitude to go through chemistry in college.

But I have struggled with the problems, and as I'm sure you all know, I frequently have chances to talk with you who are scientifically trained. The great challenge before EPA is to try to bring together with the broad desires of the public the scientific understanding of problems which permits sound technical judgments on hazards or benefits or other aspects of environmental pollution that find themselves formulated as laws, and to resolve these matters through sophisticated adjudicatory proceedings and other means required by a regulatory structure.

When EPA was formed, the emphasis that had been placed on regulation in the air pollution, water pollution, and pesticide programs was probably accentuated, and this has simply intensified the need to bring together a wide diversity of backgrounds and skills so that judgments can be made which reflect all of the factors which must be considered to do our job.

I gather that you all have had a long hard day of pounding away at some of these tough questions, and I want to take advantage of this occasion to talk a little bit about the pesticides program of the Agency and possibly give a chance for those of you who are interested to raise some questions and have, perhaps, a little dialogue.

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*Deputy Administrator, EPA

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There has been a very substantial amount of criticism addressed to EPA in regard to the way we have run the pesticide program. This has culminated, as of maybe 2 months ago, in a series of amendments proposed to the pesticide law itself, which was before Congress only in the sense that it required an extension of the authorization for funding. That does, however, require a legislative action and provides an occasion to at least consider the law, and a great many amendments were proposed.

Last week, a further and substantially more major amendment was proposed that would require concurrence from the Secretary of Agriculture before any decision was taken by EPA that would go toward terminating use of a pesticide or before regulations were issued.

I think that what we are looking at is a buildup of frustration over a variety of items and, generally, all contributing to a certain reaction of people feeling that this was a time to take a crack at the law and at EPA's management of the programs under the law. You are, I'm sure, familiar with virtually all of these, and many of you are much more familiar with them than I, but they involve the tussock moth problem, the fire ant problem, basic challenges to the way EPA has made its decisions, frustration over the coyote management, predator control actions, questions as to the DDT decision, and questions on the banning of other pesticides, and the culmination of these is focusing attention. One of the other issues is implementation of the program requiring applicators to be certified, uncertainties as to what burdens that will put on the farmer, and whether that is going to cause a great disruption.

Underlying these specific questions is a much more general question as to whether EPA, in implementing this program, is going in a direction that is incompatible with the continued good health and high production of the agricultural industry of this country. Also involved is a very strong feeling that there is not an adequate foundation in scientific judgment to support the decisions that the Agency is making.

To put it more simply, I think that many people in the agricultural community have not recognized that there is a serious and valid basis for the conclusions that some of the pesticides do, in fact, represent serious health risks. I think the feeling is that the basis is not there to conclude that DDT, aldrin, dieldrin, chlordane, heptachlor, if you will, really do present serious health problems.

I think that this situation poses a real problem to the Agency, and it's very clear to us that in some degree and at some points, we or the Agency as a whole haven't done the job we have to do -- whether it is a matter of not doing the job in terms of reaching the decisions, or whether it is more a matter of not doing the job in the way we reach the decisions, or not doing the job in the way we communicate to the rest of the country the basis for reaching the decisions.

In part I think we all have to recognize that what we're dealing with are questions on which firm judgments are exceedingly difficult to reach. It is not a simple matter to decide whether a health risk is associated with a given pesticide, how serious that health risk is and, ultimately, whether the risk that we're talking about is of such importance as to outweigh the benefit from use of that pesticide. There is a whole range of questions. None of them are simple, and when you put the whole thing together, it is very complicated and difficult. This is almost bound to be the type of thing in which very wide differences of opinion exist.

But notwithstanding the inherent complexity and controversiality of the problems, our job still is not only to make decisions that are right, but also, insofar as we can, to work together to bring the facts into a process whereby there can be some consensus and acceptance of the validity of our decisions.

A couple of things relate to this which I think are very important. One is the question as to the process within the Agency and I spoke of this element at the very beginning -- the relationship between the lawyers and the scientists. This is inherently difficult, but I think that the extent of the difficulty becomes exaggerated by the nature of the process.

The decisions that we reach will be made through a regulatory or adjudicatory process, and they will be litigated, and the articulation of the decisions tends to be primarily a legal matter. I want to distinguish very carefully between the articulation of the decisions, or the formal procedures through which they're reached, and the decisions themselves. The decisions themselves are not primarily legal decisions. But the explanation that is given, the language that Russ Train uses as he reads the press release or explains it, is heavily weighted on the legal side, because the questions are going to be litigated and you just can't get away from that.

At the same time, I want to give an assurance that in our minds we have a very full recognition that the decisions made are not going to be sound decisions unless they rest on an absolutely solid scientific basis. And they clearly can't do that unless they are reached, basically, through scientific research and decided upon by the Administrator relying primarily on scientific advice rather than legal advice. I think that to a very great extent we have received good scientific advice on the decisions, and have received that to probably a greater extent than may be recognized throughout the Agency and throughout the world of people who follow these decisions and are interested in them.

Then, beyond the issue of the process that we're going through and how we decide these things is really the question of what is the record. I think there is a tendency to feel that EPA is going off half-cocked, and on this I would simply say that the intention of the leadership of the Agency has been to proceed cautiously, to look at individual pesticides one at a time, and to take action only after a very thorough amount of scientific work has been done. In this regard I'm really not talking just about the cancellation-suspension actions.

I remember the day after EPA was formed, when we received a petition from the Environmental Defense Fund calling on us to ban a group of pesticides, and we had before us at that time the Mrak Commission recommendation listing nine pesticides which, on the basis of a substantial amount of strictly scientific thought, the members of that Commission recommended did represent a health risk and should be phased out within 2 years.

We have, in a sense gone to work on that list, but we have gone to work cautiously. Perhaps some would say too cautiously, with the result that at this point 4 1/2 years after the Agency was formed, there have been four or five of those pesticides on which we have moved to the point of taking action and others are still fully in use.

In the other actions and decisions that we've made, we have attempted to proceed with a real sensitivity for the need to use pesticides throughout the society and the need to weigh our decisions carefully. And, as I say, I think the record supports that.

I also strongly feel that the record of EPA in running a pesticides program has been a good record. A tremendous amount of hard work has been done to improve the record of receiving and reviewing and acting upon applications for registration of pesticides. And the general speed of making decisions and processing these, as I think you all are aware, has been improved very substantially in the last 3 to 5 years.

The enforcement program, which was almost a scandal when EPA began, has taken hold in what I think is a constructive and very successful way, and in other respects also I think that the program is going well.

Now that brings me, in particular, to what you are working on at this conference, and that is the substitute chemicals effort, and I do want to emphasize our interest in this and our concern for it and, I might add, my delight at hearing — at least from those I spoke to — that the general reaction to today's session has been very positive, and that the feeling — again from the people I talked to — was very positive as to the degree of progress that we seem to be making in developing a good effort in the substitute chemicals field.

Certainly everyone recognizes that pest control is essential to agricultural production, and agricultural production in high volume is essential to the well-being of this country. Not only our own welfare but also that of much of the rest of the world is directly dependent upon it, and this country must remain strong in agriculture. It is strong today, and it isn't going to change, and EPA is not going to change it. But we are in a process of making some changes in the pesticides used in the country, and as health effects are found and some pesticides are abandoned, there have to be substitutes to take their place.

I think the work of the Substitute Chemical Program to anticipate what substitutions essentially are likely to occur and to try to have an advance understanding of any problems that might be associated with the pesticides that will come into greater use and to develop new pesticides wherever possible is extremely valuable work. It will not have an immediate payoff. Like most of the scientific work that goes on in the Agency, in this Program we're often looking at a long period of time -- between when the work is done and when it has a benefit in the practical world in a broad-scale way. However, despite the time involved, the Program is meeting an absolutely indispensible need if we're to keep going and handle the problems without disruptions.

QUESTION: What is your prognosis on the 90-day continuation of FIFRA?

MR. QUARLES: I don't know and probably would be a fool to go very far out on a limb in predicting. It does seem to me that the situation is fluid and could go perhaps in one of a variety of directions. So far as I understand it, nobody in the Congress is seriously thinking that the Program should stop or seriously questioning the amount of money that is needed to run the Program. The funding is going to be governed by the appropriations bill, and I'm sure the authorization will be provided to cover essentially whatever is required.

So the only question is, when will Congress complete its work so that the full authorization will become available, and this is very important in regard to our being able to go ahead and commit the money, particularly for the state programs for the applicator certification, as well as right across the board.

So the timing is important, and secondly, there is the question of what changes might be made in the statute, and it's clearly too early to tell on the changes.

On the timing, I would guess probably that there will be a strong effort to wrap the thing up in September and to finish it at that point and not to have to go into another continuing resolution. Now whether or not they can do that will depend on whether the people, particularly in the House Committee but also on the Senate side, will be able to fairly quickly reach agreement on a limited number of amendments. I think there is some possibility that the critics will say: Well, if you do this and this and this, then we'll be satisfied and you can go ahead with the program basically as it is.

On the other hand, if the thing opens up into a long, extended acrimonious debate with all sorts of amendments being proposed and taken seriously and really thrashed out, and if it develops momentum in the House Committee to really, in a sense, rewrite a good part of the law, then you are going to go over on the Senate side where they presumably would have different judgment on a lot of those issues and go into a conference committee which would be a very extended procedure. I would expect just from watching Congress that you couldn't complete that type of a process, not only not by September, but by a year, and I think we would be basically going from hand to mouth throughout the whole fiscal year. I don't think that's likely. It's a prospect, however.

QUESTION: So what do you think is the impact?

MR. QUARLES: Well, you know, I think it's unfortunate and the timing couldn't have been worse, and there was a good deal of thought on the 12th floor that we ought to just shove this back under the rug and pull it out 4 months later to make the decision. And Russ Train, in what I think was a fairly brave decision, concluded he wouldn't handle it that way. Others might call it a foolish decision, but the circumstances were such that we felt we didn't have any justification for not issuing the notice of suspension and starting that process. If we came in 4 months from now and did that, there would be no way to justify the fact that we waited 4 months, other than that we had done it strictly for purposes of affecting the course of the legislation, which Russ did not feel he could use as a basis for the decision.

I think that there will be a certain tendency on the part of some people to feel that this decision was made in reaction to the situation on the Hill, and it may be some time before that can be clearly documented not to have been the case. It was not the case. But partly because people in Washington are suspicious and partly because it does, in a sense, raise the stakes of the game, it may tend to create more of a risk to people really pushing hard for broad amendments.

In this respect I guess I would just have to say that I think today's development is essentially a step in the wrong direction, but one that we felt we had to take.

The decision made today is one on which we did not go outside of EPA at all, and let me explain that a little bit. We made a decision last November to issue a notice of cancellation, and that decision rested on a fairly extensive amount of scientific work which involved input from a variety of sources and discussion with a variety of people outside the Agency.

Once that decision was made, we began a legal proceeding, a formal administrative adjudicatory proceeding, and the Administrator thereby becomes prohibited from any ex parte discussion of the matter. What that means, in simple terms, is that he can't talk about this with anybody, or he has to act on the record of the matter as it is developed in the proceeding. And so the requirements of that process are such that the information essentially has to be bundled together and sent up to him and it has to be a decision that is made very largely by himself alone, or in discussion with a very limited number of people.

Now the other side of that is that this decision does not by itself decide anything. It simply means that there will be an expedited proceeding, which will take place over the next 3 or 4 months, at which the evidence will be presented in the usual way that the law provides for in this type of a matter, and then a decision will be made by the Administrator.

QUESTION: The EPA has been criticized from many quarters, I think externally as well as internally, as being an Agency where lawyers are making scientific decisions. I'd be interested in your opinion as to whether or not you feel there is indeed a piece of truth in that, and if so, how can the situation be rectified in the sense of indeed getting more of a scientific input at the decision-making level?

MR. QUARLES: I guess my answer would be that there is a piece of truth in that. Possibly you could turn it around and say scientists are making legal decisions. There would be a piece of truth in that as well.

But I don't mean to be flippant, because I think that there is a real difficult job to be done to be sure that you have the legal part of the decision and the scientific part of the decision kept in the right balance. The clear and strong need is to be sure that there is just a very complete degree of discussion between the legal people and the scientific people, and that is inhibited when we come to a decision such as made today. However, I would again emphasize that important as are the decisions to issue a notice of suspension, they are only one chink in the process, and the decisions to start the process, and really all of the input, are much more balanced.

So I guess that what I would say in short answer is I think it is a problem. I think it's one that we need to work on. I wouldn't try to say it's been handled in the best possible way, although I think it's being handled probably better than a lot of people would feel, who may not be close to the process and simply are conscious of the fact that Russ Train is a lawyer and I'm a lawyer. The feeling is we announce it and it was probably all lawyers who were doing the deciding.

When it gets to the point of the final policy judgment being made, that policy judgment is a matter of balancing fairly broad social considerations against certain assumptions of fact. The facts are scientific, and the assumptions are generated almost wholly through the scientific staff.

QUESTION: Mr. Quarles, could I ask you to change your focus a little and speculate, if you would, on toxic substances legislation and perhaps the implementation. I know that it's very premature, but a lot of us here are going to be very interested in what's going to be done.

MR. QUARLES: Implementation of the Toxic Substances Act, if it comes along?

QUESTION: Well, the potential for passage and then the implementation.

MR. QUARLES: I think the Toxic Substances Bill is going to be passed. Of course it may not be, but I feel it will be passed. The level of seriousness of the problem is such that there is a genuine need for toxic substances legislation, and the public awareness of it is very high, and it just seems to me the momentum is moving in that direction.

Now, one of the problems is to get out of Congress a reasonable solution to a problem. You tend to get either no solution or an excessive solution, because in the Congressional process frequently there are the advocates and there are the opponents, and one side or the other wins, and if the advocates win, you get a fairly ambitious program, and if the opponents win, you get nothing.

And our Agency, as to its desires, falls in the middle of not desiring to have a really ambitious program, and it's very clear to me that we don't have the capability to carry out a fairly ambitious program and won't. This is something where very clearly you've got to start the snowball small and there's an awful lot to learn in these areas. I think that one of the reasons we've gone cautiously in some of the pesticide matters is that there is so much to learn, and the whole body of knowledge is such that there are a lot of risks. And in the area of measuring the seriousness of medical risks, as we get more into the field where it is determined that more substances cause cancer, we're going to really have to face the question of whether you can say just because something causes cancer we're going to abolish it altogether, and we just haven't begun to deal with those problems.

I think that if a program were passed by Congress, our approach would be to establish fairly quickly sufficient but minimal requirements for notification of the Agency of new chemicals coming on line, and to try to develop fairly quickly protocols for testing, although again I am experienced enough to know that doesn't happen overnight. I would expect that it's going to be quite a job before we really can develop protocols that would cover a substantial part of the field, and in due course I think you'd be beginning to see some actions to restrict the use of certain chemicals.

I think that if there would be any fear that enactment of that legislation one year would lead to the abolition of a variety of chemicals the next, that would be wholly unrealistic, whether you would regard that as good or bad. I think that just isn't going to happen, because the knowledge wouldn't support it, and the wheels of government don't move that fast. But there certainly are several problems: PCB is a good example, as John Buckley and I were discussing earlier. There are others involving some problems we really can't deal with without that legislation, and I think if we could get the legislation and begin down the path, we and the public would be better off.

Let me simply say I've enjoyed very much the chance to be with you. I very deeply appreciate the work that went on today and the work in this program, and I wish you well with its continuation and generally thank all of you for the chance to chat with you.

RAPID SCREENING, MODE OF ACTION, AND INFORMATION TO DEVELOP GUIDELINES FOR THE REGISTRATION OF NEW GENERATION PESTICIDES

Dr. William G. Phillips*

Pheromones are naturally occurring chemicals secreted to the outside by an individual and received by a second individual of the same species in which they release a specific reaction, such as attraction toward the opposite sex.

Generally, the development of pheromones into a chemical system for pest population manipulation, such as mass trapping or disruption of pheromone communication, initially involves chemical characterization of the pheromone system, chemical synthesis, and laboratory and field documentation of the behavioral responses elicited by the pheromone. Once the structure and the evoked biological responses are described, evidence of the effectiveness and usefulness of the pheromone for population manipulation must be established through field testing under natural conditions.

Population Monitoring

The use of pheromone-baited traps for monitoring the presence and estimating the abundance of pests has found ready acceptance in integrated pest management. Monitoring generally employs at very low rates a natural compound that is indistinguishable in the environment from the naturally secreted pheromone and undetectable by chemical instrumentation. This pheromone usage is not designed and does not carry commercial claims to reduce population levels; consequently, monitoring systems are not regulated by EPA.

Population Suppression by Mass Trapping

Several distinct methodologies for pheromone utilization in direct population manipulation have been described. The technique of mass trapping utilizes compounds which lure one or both sexes to a mating and/or aggregation locus. In mass trapping these compounds are emitted from a dispenser and the attracted pest becomes ensnared in a sticky trap or a device of similar principle. Success of this method depends upon removal of a sufficient portion of the pest population so as to reduce damage or nuisance to an economically or medically acceptable level.

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Efficacy in mass trapping involves not just the description of the actual number of pests captured in a test, but, additionally, it requires some independent estimate of the effect on the total pest population and/or of the damage reduction. It is important to note that these baited traps can be removed after use, thus eliminating direct contact of the pheromone with the environment. In some successful mass trapping experiments, the quantity of pheromone used per acre was less than 0.04 gram (0.00009 lb) or roughly 1/10,000 the quantity per acre for several conventional pesticides (economic poisons). In the case of other pest species, the total amount of pheromone per acre could be substantially less than this amount.

Population Suppression by Disruption of Communication

Population manipulation involving a disruption of communication is dependent upon atmospheric permeation with a sufficient concentration of communication component chemicals to prevent or greatly alter the pest's olfactory perception and orientation toward the natural pheromone sources. Successful communication disruption thus generally prevents crop damage in the following generation by reduction or elimination of mating in the present generation. Efficacy evaluation again requires precise sampling of the total pest population and/or crop damage. Catches of pheromone-baited or organism-baited traps or mating incidence in the treated areas are evidence supportive of efficacy, but by themselves such data do not constitute a demonstration of efficacy.

One technique for dispersal of the pheromone into the atmosphere is emanation of the compound from point source dispensers. Such evaporating devices can be employed at a set number per unit area and are recoverable, i.e., can be removed after use, so that the pheromone is dispersed only into the atmosphere and not sprayed directly onto the foliage, crops, soil, and target or nontarget organisms.

Another method of pheromone application is similar to that used for conventional pesticides. In this procedure, a pheromone formulation (involving microencapsulation, wettable powders, or other volatile release matrices) is sprayed with standard pesticide equipment (air blast, LV, ULV, etc.).

Experiments conducted to date indicate that rates of only 10 grams (0.02 lb.) or less of pheromone per acre per application may be more than adequate for communication disruption for several weeks. The specific test protocol necessary to demonstrate efficacy will be dependent on the characteristics of the pheromone compound, the nature of the manipulation technique chosen (mass trapping or disruption with either point source or a sprayed formulation), the nature of the crop, the timing of the application, and the biology of the organism.

Insect Growth Regulators (IGRs) are chemical entities designed to control insects and therefore should fall under the general rules for registration of pesticides. However, certain modifications in the Guidelines are essential to facilitate registration of IGRs and other types of chemical control agents with an essentially slower mode of action and a greater selectivity than are present in standard pesticides. The slower mode of action does not necessarily make a control agent less effective in terms of the number of pest insects eliminated, but if the control effect is aimed at a specific stage, the IGRs may have to be applied earlier. They should be regarded as preventive rather than short-term curative, but can ultimately produce quantitatively comparable results. A greater selectivity can result in a long-term beneficial effect through the more efficient cooperation of beneficial insects, such as predators and parasites, than is seen with broad-spectrum compounds. The possible impact of a combination of these two features has not yet been fully assessed but may well turn out to be very beneficial. The consequence of these features is that the usefulness of IGRs is not so much in immediate reduction of the number of feeding pest insects, but rather in population control one and more pest generations after the application.

It should be recognized that insect pests are diversified from monovoltine species to species with successive generation cycles during one vegetation season. In the latter case, the ultimate effect of population control is not very different from that of an acutely toxic pesticide, although selectivity may add a long-term effect bonus to the treatment. In these cases, the present Guidelines for evaluating field performance are adequate, if only the evaluation periods are extended sufficiently to cover at least one, but preferably more than one, generation cycle of the target pest after the start of the treatment. With monovoltine pests, particularly those with high dispersal rates, population control is not a task for individual growers, and field efficacy is difficult to prove under natural conditions because very large test areas, not amenable to the usual experimentation designs, are required. The problems encountered can be compared with those of the use of pheromones for insect control, pest reduction through sterile male release, etc. However, between these extremes, many situations may be identified in which IGRs may play a useful role, particularly if the trends continue in the adoption of modern pest management techniques through integrated control.

In order to utilize pheromones and IGRs as possible substitutes for other pesticides which are considered to be potentially hazardous to man and the environment, the obtaining of information to enable EPA to develop registration criteria has been considered essential. Such guidance would provide a means of evaluating the efficacy and safety of new generation pesticides, which, in turn, could lead to the practical application of these compounds as substitutes under the Substitute Chemical Program. The utilization of these materials as pesticides could further contribute significantly to a reduction in the pesticide load entering the environment.

Appropriate methods will be evaluated by the contractor to test these compounds in the determination of their toxic and pharmacological effects and their effects on the development and reproduction of target and nontarget organisms. Upon receipt of this material the Criteria and Evaluation Division will develop the Guidelines for registration of these new generation pesticides. Also, in order to rapidly evaluate the efficacy and degree of hazard to man and the environment of the large number of new generation pesticides now in the research and development stages, rapid screening techniques must be established. Because the field of new generation pesticides is novel, considerable technical detail has been provided in the background.

"Rapid Screening, Mode of Action, and Information to Develop Guidelines for the Registration of New Generation Pesticides" is the project title. The prime contractor is the Zoecon Corporation of California. The Zoecon Corporation was selected to satisfy the needs of EPA in providing these scientific data and technical information on the basis of three major factors: 1) expertise, 2) experience, and 3) facilities and services.

The scope and intent of the contract is to provide scientific data and technical information to enable EPA to develop registration guidance and criteria for insect growth regulators and pheromones.

As used in the "scope of work" for this contract, the term pheromone includes any chemical mechanism or device which modifies the behavior of a pest. Therefore, chemical attractants discovered by empirical screening, host plant odors, constituents or mimics, and a variety of compounds which modify insect behavior are included under the term pheromones.

An insect growth regulator is defined under the contract as "A Substance or Composition Which Exerts Indirect Lethal Effects on an Insect in a Manner Which is Critically Dependent on the Developmental State of the Insect." This includes juvenile hormones and other compounds which affect insect growth and development.

The basic difference between natural pheromones and juvenile hormones is that pheromones are emitted to the outside of an insect to elicit a behavioral response, whereas hormones are emitted internally to elicit tissue responses in the initiation of metamorphic changes. Natural compounds are difficult to quantitate in any manner which could be commercially feasible, whereas synthetic pheromones and growth regulators can be manufactured, produced, and utilized in a commercially feasible manner for the monitoring or suppression of pest populations.

The technical information and scientific data provided by this contract are the results of the compilation and evaluation of data and information from many sources. These sources include 1) interviews with experts working with IGRs, pheromones, and related disciplines; 2) the results of rapid screening studies; 3) a current reference collection which is specific for IGRs and pheromones; and 4) Zoecon expertise.

Interviews: Approximately 146 scientists have interviewed on the basis of published or reprinted expertise related to the basic or applied aspects of IGRs and pheromones. These represented industry, universities, and Government agencies. Interview questions were derived from the Registration Guidelines in a manner to prompt discussion of any potential differences for IGRs and pheromones. Separate questionnaires were used in each of five areas: 1) basic research -- IGR and pheromone; 2) applied research -- IGR; 3) applied research -- pheromone; 4) industry -- IGR and pheromone; and 5) toxicology laboratories. Interviews were conducted in person whenever possible.

Rapid screening studies: Insect growth regulators are mimics of naturally occurring compounds found only in arthropods and have been considered to be relatively harmless to vertebrates, including man. On the other hand, IGRs may be analogs of hormones of various types occurring in other arthropods. It has, therefore, been considered of primary importance to determine if they 1) exhibit any interference with mammalian activity or human toxicity, or 2) produce any adverse effects on crustaceans or other species of nontarget arthropods. Only IGRs and chitin synthesis inhibitors were screened for safety to humans and other arthropods under this contract. An additional screening study was also conducted to determine whether IGRs would prove effective in the control of stored product pests.

Mammalian Hormonal Screen

Rapid screening studies were conducted on five insect growth regulators to determine any evidence of interference with mammalian endocrine activity. The subcontractor for this study was the Institute of Hormone Biology, Syntex Research Center, Palo Alto, California. The five compounds screened were Zoecon Altosid; Zoecon ZR-777; Stauffer R-20458; USDA AI-3-36093-HC; and Thompson-Hayward TH-6040. The following methods were used to detect any adverse effects on mammalian endocrine hormonal activity.

1. Mouse estrogen assay in which the test materials were given subcutaneously to immature female mice. The endpoint was the uterine/body weight (mg/g) ratio. Each compound was tested using total doses of 0.5 and 5 μg. The test also included one control (vehicle only) group as well as groups receiving estrone at 0.5 and 0.2 μg. Each group contained 10 mice.

2. Rat androgen-anabolic assay in which test materials were administered subcutaneously to immature castrated male rats. The endpoints were the tissue ratios (mg tissue/g body weight) of the following tissues: ventral prostate, seminal vesicles, and levator ani. Each compound was tested using total doses of 0.2 and 2 mg. The test also included one control (vehicle only) group as well as groups receiving testosterone at 0.5 and 2 mg. Each group contained six rats.

3. Glucocorticoid activity test for thymolytic activity in which immature adrenalectomized male rats received the materials subcutaneously. The endpoint was the thymus/body weight ratio (mg/g). Each compound was tested using total doses of 0.4 and 4 mg. The test included one control (vehicle only) group as well as groups receiving hydrocortisone at 1 and 4 mg. Each group contained seven rats.

No evidence of any interference with mammalian endocrine hormonal activity was exhibited by the screened compounds. Copies of the results on this study are available to those who are interested.

Crustacean Screen

Rapid screening studies were conducted on three insect growth regulators to determine any effects on the growth and development of the juvenile stages of crustaceans. The subcontractor for this study was Bionomics, EG & G, Aquatic Toxicology Laboratory, Wareham, Massachusetts. The three compounds screened were Altosid, TH-6040, and R-20458. The invertebrate test species were 1) *Daphnia magna* and 2) the grass shrimp, *Paleomonetes pugio.*

Although the study on *Daphnia magna* has been completed, there are some questions relating to techniques used in the study which have not been answered. We, therefore, do not wish to report any results at this time.

The tests on *Paleomonetes pugio* are still in progress. Some difficulties were experienced with the reproduction of this species but work is in progress using field-collected gravid females. When reports of these studies become available for distribution, they may be obtained by anyone who is interested.

Stored Products Screen

Rapid screening studies were conducted on four insect growth regulators to determine their effectiveness in the control of stored product pests. The subcontractor for this study was Dr. R. G. Strong, Department of Entomology, University of California, Riverside. The four compounds screened were Zoecon Altozar, Altosid, R-20458, and TH-6040. The species of stored product pests which these were tested against were 1) the granary weevil, *Sitophilus granarius*, and 2) the rice weevil, *Sitophilus oryzae*. Copies of the results of this study are available to those who are interested.

Current Progress

The contract is essentially completed except for the crustacean screen with *Paleomonetes pugio*, which is scheduled to be completed by September 30, 1975.

The Criteria and Evaluation Division has begun to develop guidance and criteria for the efficacy and safety evaluation of pheromones. The purpose of this guidance will be to assist registrants with the registration requirements for developing and testing these compounds and to assist the registration process with the evaluation of such products when submitted for registration.

This "Guidance and Criteria" package will be developed in a separate document paralleling the Registration Guidelines in format, but applicable specifically to the development and testing of these compounds in support of registration.

This will further enable us to circulate and work on this document within the Registration Division until the requirements are suitable to both the Criteria and Evaluation Division and the registration process, thereby preventing the problem of constantly disrupting the broad Registration Guidelines. The anticipated completion date for the pheromone guidance and criteria will be the end of the current calendar year.

The development of guidance and criteria for the efficacy and safety evaluation of IGRs will not get underway until the remaining crustacean screen has been completed.

Recent scientific studies on the mode of action of TH-6040 have shown that this potential insecticide acts by inhibiting the synthesis of chitin which occurs in immature insects just prior to molting. Whereas TH-6040 was initially classed as an IGR, its mode of action is now known to differ from IGRs as well as other insecticides. Separate guidance and criteria for the efficacy and safety evaluation of materials of this type are presently being considered.

COMMERCIAL FEASIBILITY OF NEW GENERATION PESTICIDES

Peter D. Stent*

The title of this contract with EPA is the Commercial Feasibility of New Generation Pesticides. From the objectives listed below you can see that we are attempting to view commercial feasibility from the standpoint of private companies looking at alternative investment ventures in products which were termed new generation pesticides.

1. Determine what new products or pest control mechanisms are technically potential substitute chemicals, substitutes for chemicals, or complements to chemical pesticides.

2. Determine the critical factors affecting the commercialization of general products or mechanisms defined in 1 above and specifically for a selection of products either presently commercially available or with a good potential for commercial availability in the near future.

3. From 2 above, determine the incentive and/or disincentives for industry to commercially develop these products or mechanisms, with emphasis on the incentives or disincentives which can be influenced by Federal policies.

4. Determine policy alternatives that could improve the technological and economic environment for the development of these new pest control materials and methods.

There is a definitional problem here on what a new generation pesticide is, and it's beyond the scope of this discussion to go into that. We felt more comfortable with the terminology looking at the commercial feasibility of new pesticide products, regardless what generation they might fall into. As we view it, the new products coming onstream which we analyzed through our very rigorous methodology, which I'll describe later, are really no different than a lot of the products in the past and basically follow a continuum of development. We are

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looking at a time period which just extends 10 years from now, 1975 to 1985, and we are looking at the new types of products which might substitute for some of the presently used products.

One of the first things we did in assessing commercial feasibility was to develop some sort of systematic way of structuring the problem as a commercial company might do when they are looking at alternative ventures. We began, as I'll show you in the method of approach, fairly early in the study to realize that we had to take a rather unique view and to develop a unique method to handle the very wide spectrum of products in this category.

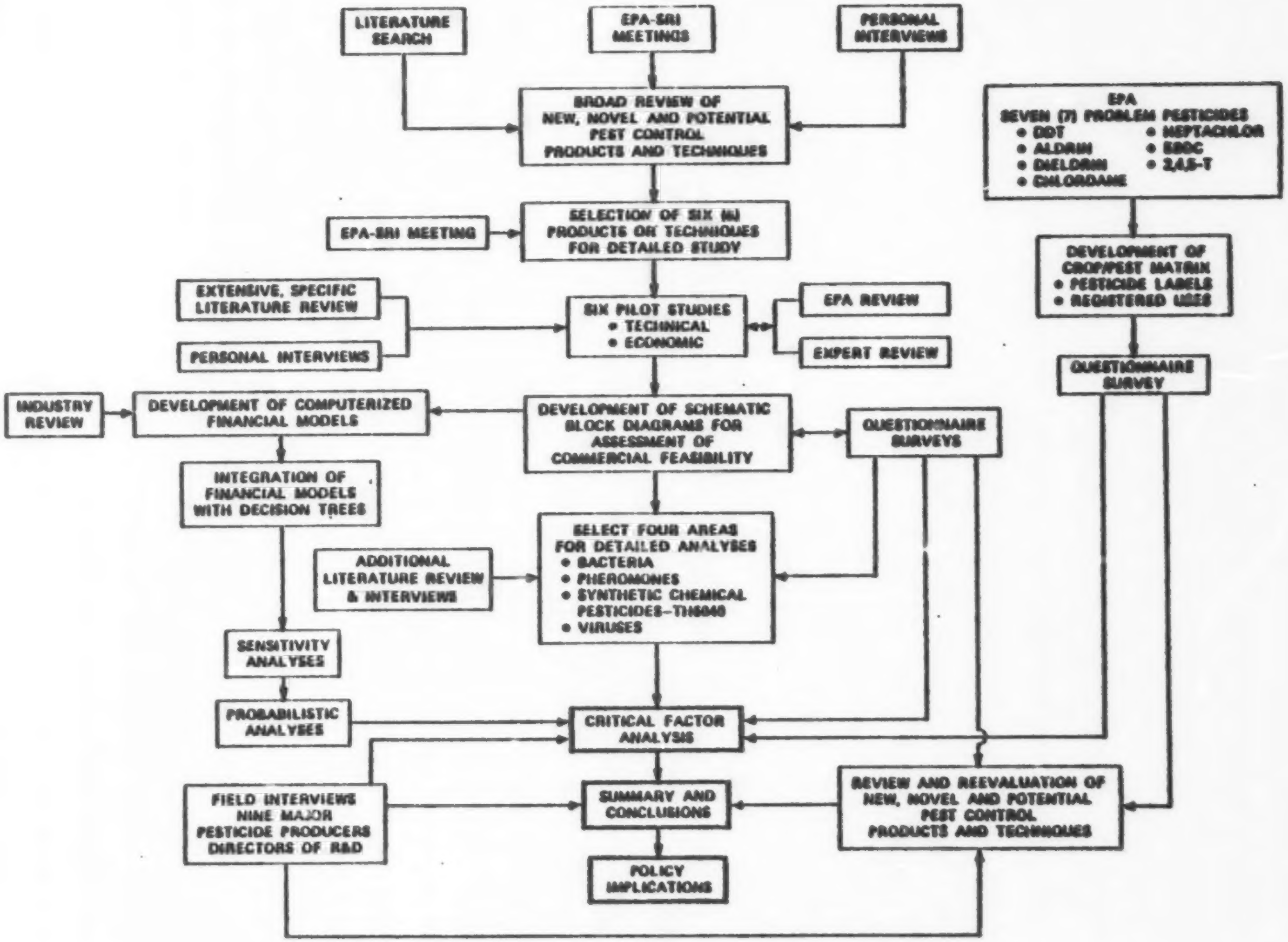
The approach we decided to take was basically a rather new type of decision analysis methodology which I will describe in detail and give the results of later. The first part of it is a deterministic phase in which we structured the pertinent issues and concerns that a private company would consider when they are looking at the potential for perhaps exploring new products or developing them for a commercial market.

Figure 1 is quite complex, and behind it are several more, and the entire thing is computerized in algorithmic fashion so that it can be used with pertinent data input to this system. There are basically three components to this structural diagram. On the left are the market components which are basically the economic components that we would call state variables, which are outside the control of the producer per se. He has to operate within that environment; he really has no control over that. Then we have a fundamental research and a product research and development sector, which effectively is undertaken once the potential producer makes a decision to commit because he has evaluated the market side of it and feels that there is sufficient potential to proceed.

The third segment is the production and distribution cost model, and each one of these three models was expanded in considerable detail, as I said, into mathematical formulas which interrelated.

Figure 1

SCHEMATIC OF METHOD OF APPROACH



LITERATURE SEARCH
EPA-SRI MEETINGS
PERSONAL INTERVIEWS
BROAD REVIEW OF NEW, NOVEL AND POTENTIAL PEST CONTROL PRODUCTS AND TECHNIQUES
EPA SEVEN (7) PROBLEM PESTICIDES
• DDT
• ALDRIN
• DIELDRIN
• CHLORDANE
• HEPTACHLOR
• EBDC
• 2,4,5-T
EPA-SRI MEETING
SELECTION OF SIX (6) PRODUCTS OR TECHNIQUES FOR DETAILED STUDY
DEVELOPMENT OF CROP/PEST MATRIX
• PESTICIDE LABELS
• REGISTERED USES
EXTENSIVE, SPECIFIC LITERATURE REVIEW
PERSONAL INTERVIEWS
SIX PILOT STUDIES
• TECHNICAL
• ECONOMIC
EPA REVIEW
EXPERT REVIEW
QUESTIONNAIRE SURVEY
INDUSTRY REVIEW
DEVELOPMENT OF COMPUTERIZED FINANCIAL MODELS
DEVELOPMENT OF SCHEMATIC BLOCK DIAGRAMS FOR ASSESSMENT OF COMMERCIAL FEASIBILITY
QUESTIONNAIRE SURVEYS
INTEGRATION OF FINANCIAL MODELS WITH DECISION TREES
ADDITIONAL LITERATURE REVIEW & INTERVIEWS
SELECT FOUR AREAS FOR DETAILED ANALYSES
• BACTERIA
• PHEROMONES
• SYNTHETIC CHEMICAL PESTICIDES–TH6040
• VIRUSES
SENSITIVITY ANALYSES
PROBABILISTIC ANALYSES
CRITICAL FACTOR ANALYSIS
FIELD INTERVIEWS NINE MAJOR PESTICIDE PRODUCERS DIRECTORS OF R&D
SUMMARY AND CONCLUSIONS
REVIEW AND REEVALUATION OF NEW, NOVEL AND POTENTIAL PEST CONTROL PRODUCTS AND TECHNIQUES
POLICY IMPLICATIONS

The entire thing we were after was a financial model which determined the commercial feasibility of a product. What we were after was when a company looks at these new products, they basically have to make a decision, and a decision, to us, implies the commitment of resources, and this commitment is basically irrevocable without a cost in either time or money.

The environment in which these decisions are made by companies can be defined by five pertinent factors. Decisions that companies must make are first made in the light of uncertainty. If the information were perfect, which it never is a company would virtually have no problem about assuring themselves of a profit, so they could obviously not worry about the decision at all. It would be made for them.

The decisions secondly are complex. As you can see here, the rather scaled-down detail of the total model shows a complexity in itself, and the tremendous detail that's behind this, as you people in industry are well aware and I'm sure everybody is well aware, makes the problems very complex. Added to this is the fact that the decisions are dynamic. They're made over time.

They are also dynamic in that, in a sense, we have to take into account the time value of money, which essentially comes in here, in that a dollar today is worth something different than a dollar a year from now or 5 years from now. So our model uses a discounted cash flow technique, which I'm sure most of you are familiar with.

The fourth factor by which decisions are made is that they are made in a competitive environment. The firms are not in isolation. They must make these decisions in respect to other products out there and other companies out there working on the same thing. This adds to their uncertainty because although there is a fair amount of traded information, a lot of the information is proprietary, and so the companies have to make certain assumptions about their competitors and competitive products.

The fifth factor in the environment in which decisions are made, which to me is probably one of the overriding factors, is that resources are finite. With unlimited capital it would be possible to play even a very dangerous game if you could play it often enough even with a small reward, if the potential for a very high reward was far down the line. It's similar to casino betting; if you can bet on black or red, if you had enough money and doubled up every time, you'd eventually come out ahead. But if there's a limit on the top, you certainly are constrained and you risk the chance of losing a considerable amount. It's the same situation for a company with a definite limit on resources making a decision about a new product in which there is so much uncertainty.

The six pilot studies listed below were both technical and economic reviews of these products.

Technical and Economic Reviews

- Altosid
- *Bacillus thuringiensis*
- *Colletotrichum gloeosporioides*
- Grandlure
- *Heliothis* spp. NPV
- TH 6040

The purpose of doing these six studies was to be sure that all the issues and concerns which surrounded decisions about commercial feasibility would be included in our model so that when we ended up with a detailed model at the end, hopefully we would not omit a pertinent issue or concern which then generated into a pertinent parameter in the decision analysis model, which then determined the commercial feasibility of these new types of pesticide products.

From the schematic block diagram in Figure 1 we computerized it, as I told you, into financial models. We then integrated the financial models with several techniques from decision analysis, starting with decision trees which allowed us to develop plausible scenarios from a base case for each of four particular products.

The four particular products we studied from each of four classes are, in the bacteria, B.T.; in the pheromones, gossyplure; in traditional type materials, TH 6040; and in the viruses, the nuclear polyhedrosis virus of the Heliothis species.

In order to generate information to go into our models and run the financial analysis, we went to several routes for pertinent information. Many of these decisions are in areas where there is tremendous uncertainty. Consequently, we went to what we considered were experts in the field to get opinions from them about uncertainty. Although on a one-to-one confrontation with some of these persons, they would not commit themselves to certain critical questions that we asked them, when they answered the questionnaire surveys, they were very, very cooperative, even to the point where they made their best estimates of things that they would probably not stand up in front of people and discuss. Nevertheless we considered them to be the most knowledgeable people in the field, and I think that when you have so much uncertainty, even in companies when they're making their own internal decisions, they have to turn to their own experts and take shots in the dark.

There is a definite way in which we were able to take away some of the uncertainty, and that is when we went with the scenario development in decision trees and were able to run sensitivities on pertinent variables which we thought affected the commercial feasibility.

Another very important segment of our study was a field interview conducted with nine of the major pesticide companies with the directors of research and development of those companies, as well as other people who sat in on those discussions. The basic purpose of those interviews was to determine what those companies were doing in the way of developing new synthetic chemical pesticides over the next 10 years, what their feelings were at present about the commercial attractiveness of the pesticide business in general, and what they considered the pertinent variables which affected their decisions to proceed with commercialization.

From the sensitivity analyses and the probabilistic analyses (see Figures 2, 3, 4, and 5), we arrived at certain critical factors for the different products mentioned and also in general for classes of products. We were able to generalize from these specifics, we think, to certain critical variables which will affect any new type pesticide product that is being considered for commercialization.

From the critical factor analysis we arrived at our summary and conclusions, which I'll say at this time are in a draft form to EPA. EPA has a complete copy of a draft report. The report has not been finalized, and I will only go over some of the general conclusions today. I'll be pleased to answer any questions or give you details on any of them.

Policy implications have not been completed but will be within a month, and the total project is expected to be wrapped up with a final report to EPA in 2 months.

In the light of uncertainty that surrounds any new product, there are a number of decisions which occur over time that can be made, and have to be made, by a company considering entering commercial production of that product. The way we went about structuring this was to develop decision trees like those shown in Figures 2 and 3. These were developed so that along any route on the decision tree you can follow any path you want.

With each one of the nodes on any one of those paths there is a specific number or dollar quantity, associated with it. It's usually a cost until we get into market size and product margin, and then we begin to generate revenues. The entire thing is then discounted, which takes into account the time value of money, and we end up on the right hand side with the profitability of the venture for that particular scenario.

To take away some of the uncertainty with each one of these scenarios, we encoded probabilities (Figure 3) to the likelihood of the event occurring. The probabilities shown here are high, medium, and low for research and development costs. These are assigned both absolute values and probability values, ranging from zero to one.

Figure 2

SIMPLIFIED DECISION TREE FOR DEVELOPMENT OF NEW PESTICIDE PRODUCT DECISION

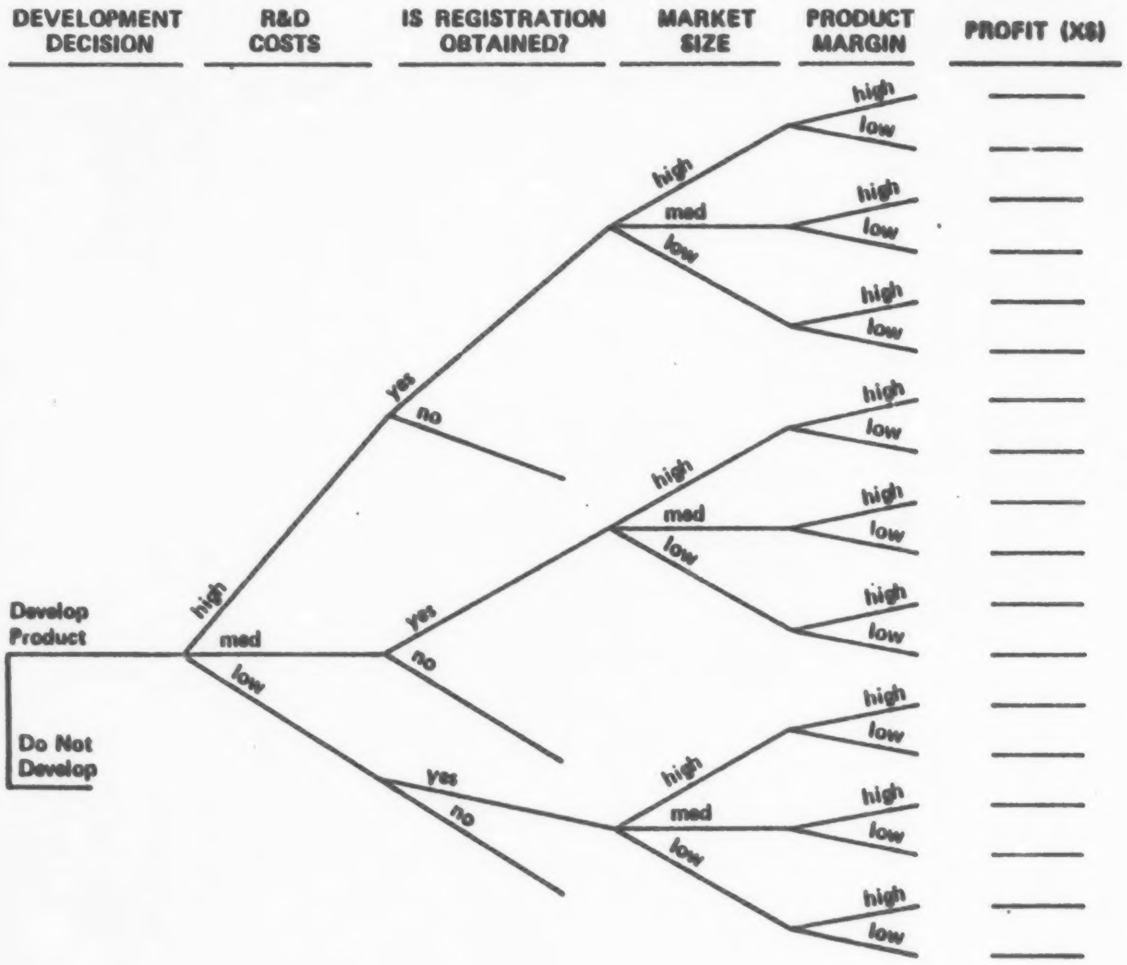

DEVELOPMENT DECISION
R&D COSTS
IS REGISTRATION OBTAINED?
MARKET SIZE
PRODUCT MARGIN
PROFIT (X$)
Develop Product
Do Not Develop
high
med
low
yes
no
yes
no
yes
no
high
med
low
high
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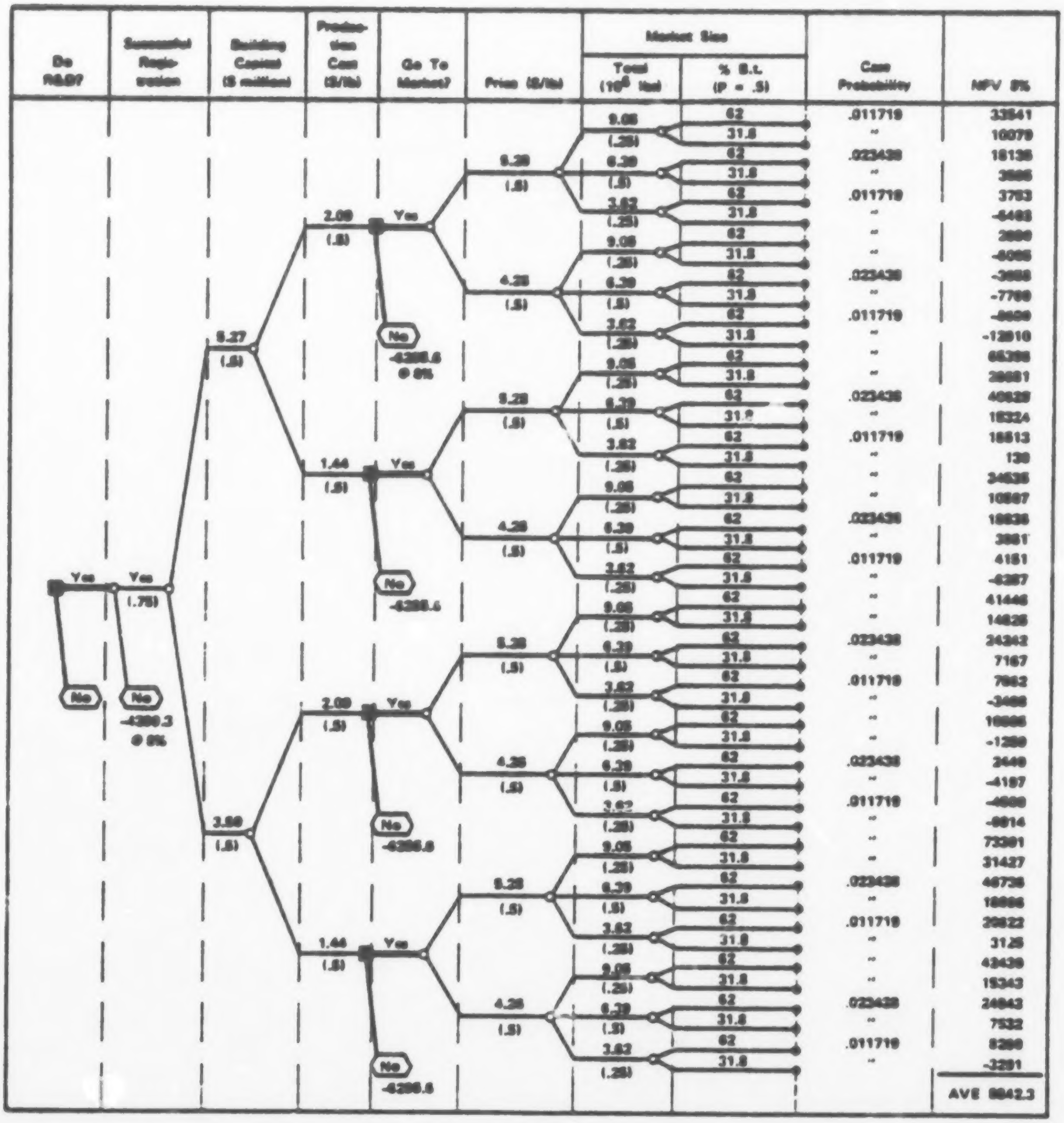
Figure 3

B.t. DECISION TREE


Do R&D?
Successful Registration
Building Capital ($ million)
Production Cost ($/lb)
Go To Market?
Price ($/lb)
Market Size
Total (10^6 lbs)
% B.t. (P = .5)
Case Probability
NPV 8%
Yes
No
Yes
(.75)
No
-4286.3
@ 8%
5.27
(.5)
3.60
(.5)
2.09
(.5)
1.44
(.5)
Yes
No
-6286.6
@ 8%
5.28
(.5)
4.26
(.5)
9.05
(.25)
6.39
(.5)
3.82
(.25)
62
31.8
.011719
.023438
33541
10079
18136
3686
3763
-6483
2886
-6065
-3688
-7769
-8609
-12810
65286
28881
40628
18324
18813
138
34635
10867
18636
3881
4151
-6287
41446
14626
24342
7167
7862
-3466
10686
-1289
2449
-4197
-4869
-8814
73381
31427
46736
18886
29822
3125
43436
15343
24943
7532
8299
-3231
AVE 8842.3

In Figure 3, you can read across the top what the pertinent decisions are that a company faces. The company can make an estimate that it might cost $2.09 a pound or $1.44 a pound, and perhaps their production experts in the company feel that there's an equal probability that it would be either one of those, depending on some particular breakthrough in production technique.

Tracing out any one of these paths, it goes through all these decisions written across the top. Eventually we end with a case probability, which is the product of all the probabilities along the path, or the scenario, and we also end up, from the financial model, with the net present value, which we discounted using an 8 percent discount rate.

What that effectively means is we compared all the alternatives with an investment in a bank at 8 percent. It was all pre-tax.

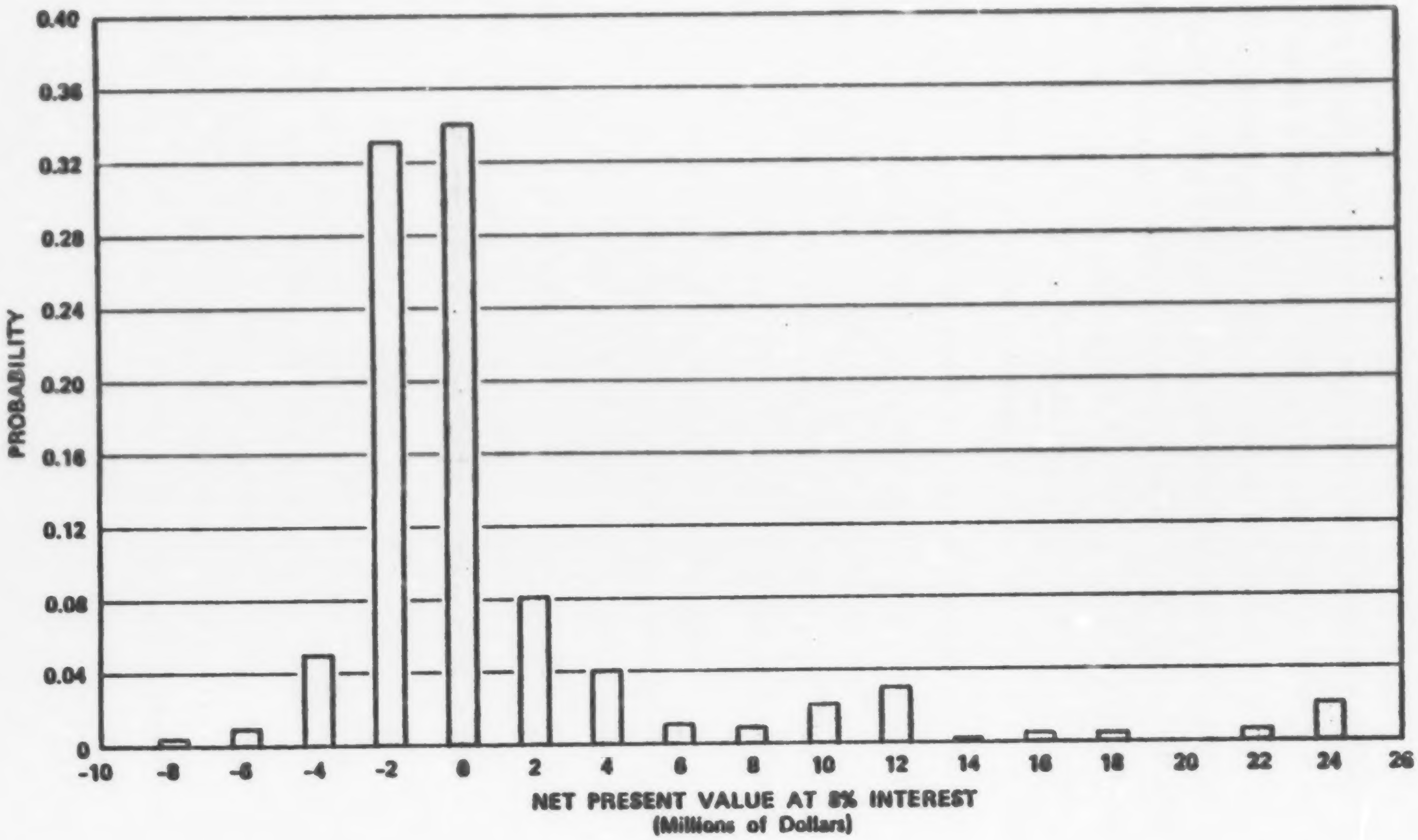
So a venture which has a net present value of zero is not equivalent to a zero return, but is equivalent to putting the same amount of money over time or capital invested in a bank earning 8 percent interest.

For each of the products that we looked at we ran a little over 650 different scenarios, which you can see is a very tedious job, were it not that it was computerized. This type of decision analysis is being implemented more and more by companies which are faced with very, very complex decisions which involve very large amounts of money and tremendous amounts of uncertainty.

The probability distribution on the present value of a pheromone venture is shown in Figure 4. What this is saying effectively is that at the zero net present value or the equivalent to an investment of the same amount of money in a bank at an 8 percent interest rate, which are pre-tax cash flows, they have roughly a 34 percent chance or the probability of attaining that result is roughly 34 percent.

Figure 4

PROBABILITY DISTRIBUTION ON NET PRESENT VALUE OF PHEROMONE VENTURE



You can see with this particular venture that the probability of obtaining very large returns is quite low. The probability of obtaining substantial losses is low. But there is a good probability of sustaining a rather large loss of $2 million, and a moderate probability of sustaining a loss in excess of that. This has implications for the types of companies that might develop these products. Certainly a small company would consider a loss of $2 million quite differently than a large chemical company that might be willing to risk the $2 million in hopes of perhaps having a payoff somewhere out here on the far end.

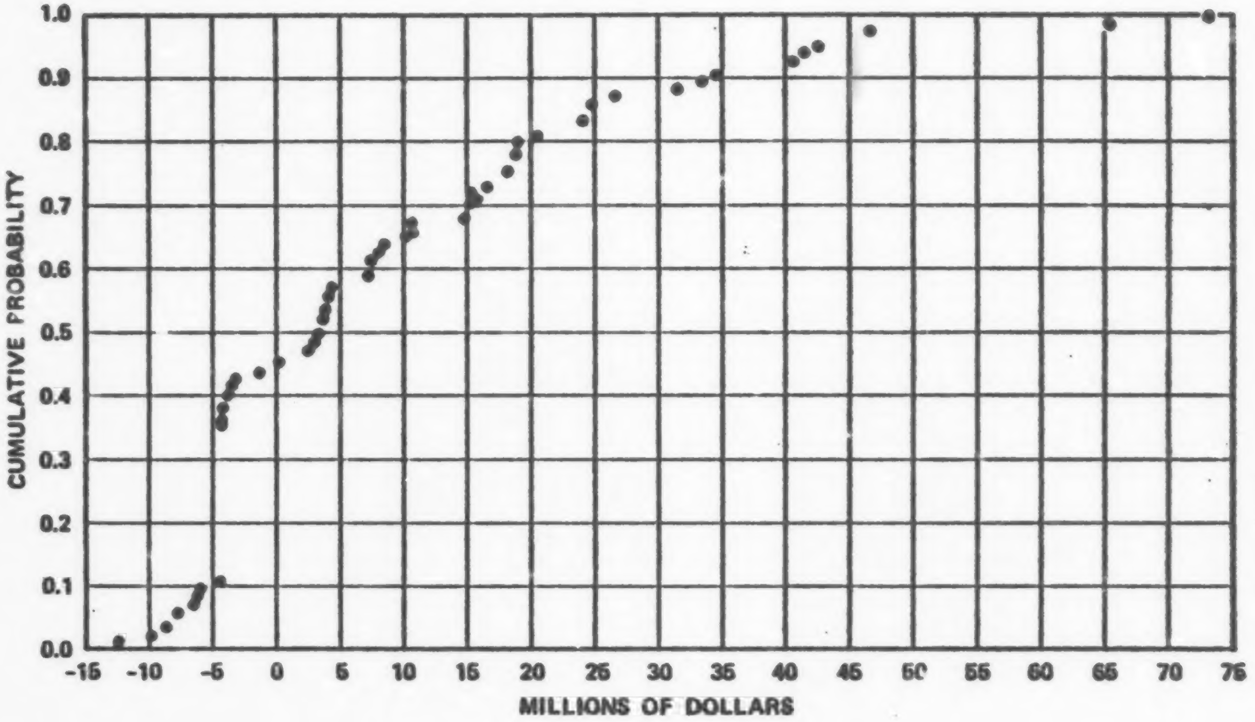
From the decision analysis model that was developed we can obtain a profit lottery (Figure 5), and this shows the cumulative probability of obtaining a given return. You can see here that if you look at the 0 or the 8 percent discounted cash flow analysis, there's about a 45 percent chance that the project will, on a discounted cash flow basis, return 8 percent.

There's a substantially good chance that it could return in excess of that. This on the surface looks like a very good venture. An additional part of the analysis goes into risk preference, and I think that's beyond the scope of today's talk, but it goes into the analysis of how companies view risk and whether they are willing, for a large payoff, to take a moderate risk. Usually most companies are willing, for a large payoff, to take a little larger risk; for a small payoff, they don't like to take as large a risk.

We can generalize three conclusions about the realm of new pesticide materials coming up. First, we found that the large chemical pesticide-producing companies find the pesticide business financially attractive and will continue to develop products and feel that through the period 1985 they will not have trouble adequately supplying sufficient materials similar to the ones developed in the past with new ones coming along, such as TH 6040, to protect our food and fiber.

Figure 5

PROFIT LOTTERY (Net present value discounted at 8 percent)



The second general conclusion is that there are three primary limiting factors on products such as viruses, bacteria, and pheromones. The first limiting factor is that absolute market size is too small. The second factor is that profit margin is too small, and you cannot maintain an adequate profit margin. This obviously gets into problems in patentability, etc., but the real underlying issue is that the profit margin is small and cannot be maintained.

The third critical factor that we found is that the temporal efficacy -- and here we get back to a time thing again -- from the standpoint of the user, efficacy of a product over time and how quickly it acts and its cost effectiveness tend to limit these products, and we feel that in a 10-year span to have the farmers change, that we do not see any indication that this will be the case.

There are numerous other conclusions concerning particular products, which we will not go into at this time. The third general conclusion that we arrived at from this study was that the new products the chemical companies are presently developing may run into short-term gaps in supply and perhaps emergency measures may need to be taken to fill those gaps. However, we feel that the marketplace would adjust rapidly to any significant gap in the system, principally because of the economic factors outlined, and that sufficient returns to the chemical companies would spur them to develop products to fill those gaps.

MATHEMATICAL MODELING TO IMPROVE THE QUALITY OF ECONOMIC IMPACT ASSESSMENT STUDIES IN PESTICIDE POLICY ANALYSIS

Fred T. Arnold*

Introduction

The examination of issues relating to continuation or modification of established use patterns for pesticides must involve the calculus of both the costs and benefits associated with each use of the pest control agent. After the costs and benefits associated with the use of a given chemical have been specified, society, or its designee through public regulatory bodies, must answer the difficult question: Do the benefits of the pesticide outweigh the costs? The decision is difficult and, if optimal, would require an exact specification of a number of elusive parameters associated with health and environmental effects, biological processes, and measurements of social welfare. In practice, these parameters cannot be precisely identified and society must, therefore, base its decision on the best available information and documentation.

The costs of pesticide use are generally external to market activity and are more difficult to accurately measure than are the corresponding benefits. These costs, which potentially include such areas as generally worsening health of victims, subtle ecological insults with the potential for disruption of the food chain, as well as the acute health and environmental consequences associated with misuse or accidental exposure and contamination, are not metered through the market system, thus negating a common market measure.

Further complicating the comparison of benefits and costs is the lack of precise knowledge regarding the biological questions associated with pesticides. Aside from the fact that the societal costs stemming from pesticide use are normally of an external nature, biological scientists have been unable to answer such questions as "how much" cumulative ingestion of a persistent pesticide will cause ecological or health problems. Therefore, even the assignment of market values to non-market impacts is difficult because of the inexact nature of such impacts. In the face of such an imprecise measurement, the policy maker must apply his own judgment and values to the costs imposed on society by the use of pesticides and weigh his subjective determination of costs against the best available estimate of the economic benefits which derive from use of the compound.

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Although of a different nature than those associated with cost measurements, the assessment of social benefits derivable from pesticide use has several inherent problems. Benefit-related problems are primarily data oriented and include such areas as accurate descriptions and quantification of use patterns, efficacy of alternative control agents, and marginal productivity ratings for problem chemicals. A mathematical programming model for policy analysis cannot overcome these data deficiencies, but can provide a thorough analysis on a national and interregional basis of the best available information regarding yield and substitution impacts.

Benefits are realized in the form of changes in food prices and/or quantities, and these changes must be measured in order to facilitate the "risk/benefit" comparisons of alternative pesticide policy. Research which has been supported through the Substitute Chemical Program is directed toward an improvement in the accuracy of comparisons among levels of food prices, quantities of food produced, interregional mix of agricultural activity, and land use and amounts of agricultural income which result from specified pesticide use situations.

Mathematical Models of Agriculture

Mathematical models of agriculture are tools for measuring the market effects of agricultural pesticide use. A subset of mathematical models, activity analysis, was chosen as the most appropriate tool for pesticide study because of its inherent assumptions which closely mirror the reality of the agricultural sector. Activity analysis assumes the maximization or minimization of a mathematically defined choice criterion (objective function) by the selection of economically feasible production activities from a finite set, constrained by available resources and required production (demand). The characteristics of the agricultural sector embodied in these assumptions are:

1. Profit Maximization or Cost Minimization - Economic theory and observation of agricultural activity support the proposition that farmers attempt to maximize economic profit.

2. Resource Adjustment - In response to changes in the price of inputs such as fertilizers, pesticides, capital, etc. and output, e.g., a change in the price of corn relative to soybeans or changes in livestock prices, farmers adjust both their mix of inputs and their cropping patterns in order to maximize returns.

3. Constraints - Resource constraints express the fact that economic activity requires the use of limited resources. Especially in agriculture, the limited supply of natural resources, particularly land, makes this a pertinent consideration. Constraints are defined on a regional basis to assure that available stocks of resources are not exceeded in the solution of the mathematical program.

A second set of constraints (non-physical) also limits the freedom of adjustment which farmers can make in response to varying economic signals. Unlike physical constraints such as a limited supply of land, this second set is subtle and difficult to specify. The set includes non-market influences, such as tastes and preferences, tradition, resource immobility, lack of information, and ignorance. These constraints imply that farmers consider a very limited number of choices at decision time. Further, they imply that farmers' decisions, while directed at profit maximization, may not always be optimal. They are accounted for within the mathematical model through a system of flexibility penalties which limit adjustment to mirror observed rigidities.

4. Fixed Production Requirements - The fixed production requirements embodied in the model, while somewhat at variance with demand theory, provide a good approximation for agriculture. Demands for agricultural products are determined primarily by population size and are moderated by price and income. A portion of the demand within the model is fixed by population within various geographic regions while the remainder (the particular mix feedgrain consumption by livestock and poultry) is responsive to feedgrain prices.

The particular form of activity analysis chosen for the agricultural model developed to support pesticide policy research assumes that the resource constraints and production requirements can be defined as linear functions, and that the objective function is both linear and additive. Although these assumptions are not entirely realistic, it was felt that for the present, the more general formulation of activity analysis models would not provide enough additional information to justify the increased difficulty of construction and solution.

Analysis of the impacts of agricultural pesticide policy requires that the model be both national and interregional in scope. Markets for agricultural products are national in that equilibrium prices are determined through a summation process of individual production decisions. On the other hand, the model must be regionally specific to account for the physical relationships and methodology of agricultural production which vary among regions of the country. This construction places extreme emphasis on the economic phenomenon of interregional competition which is an important characteristic of the agricultural economy.

The purpose of the model is to analyze the economic impacts of changes in the use pattern of pesticides. The approach is to compare the differences in food costs, resource utilization, location of production, and agricultural incomes under two sets of conditions: 1) the suspect chemical allowed in its historical use patterns and 2) the use of substitute chemicals.

Base Model

The base linear programming model contains approximately 22,000 activities (columns) and approximately 2,000 resource constraints and demands (rows). The activities include crop production (disaggregated by soil type and region), commodity transportation, conversion of commodities into feed nutrients, and conversion of feedgrains into corn equivalents. Resource constraints are defined for land by land class. Demands include those for specific commodities, livestock nutrients, feedgrains for export, and specific commodity exports.

Seven crops are treated as endogenous to the model. These include barley, corn, cotton, soybeans, oats, sorghum, and wheat. Other agricultural land uses are projected exogenously and subtracted from the total land base. The livestock sector is also projected exogenously and fixed at a predetermined level. The non-feedgrain portion of total nutrient demand for ruminants, non-ruminants, and poultry is exogenous to the model and fixed at historically projected levels. Net nutrient requirements stated as digestible protein and total digestible nutrients which must be supplied from endogenous crops were calculated and stated as regional demands which must be met through local production or import from other regions. Other non-feeding demands for endogenous crops, such as barley malt for brewing and corn for breakfast cereal, are projected as a function of Series E population estimates and are addded to regional demands to form the right-hand side constraints which must be satisfied. A set of activities for production of the endogenous crops by region with variable yields disaggregated by nine soil classes defines the feasible set of activities which can be used to satisfy regional and export demands (estimated exogenously). Each production activity has a corresponding budget and yield. The budgets, which are disaggregated by variable input, e.g., labor, fertilizer, pesticides, and machinery, allow the analyst easy access to the model for purposes of updating or changing the cost and/or quantity of variable inputs.

Regional Delineation

To reflect the real-world homogeneity of production functions and the national-interregional nature of markets, the 48 contiguous United States are partitioned into producing areas (PAs) and consuming regions (CRs). PAs are delineated so that a single production activity can be defined for a given crop in that area. CRs are defined to represent regions for which a single commodity market exists.

Producing Areas (PAs)

The United States is partitioned into 129 producing areas, each of which is an aggregation of counties (usually contiguous). Each PA is wholly contained within one state, and in some cases one producing area covers an entire state.

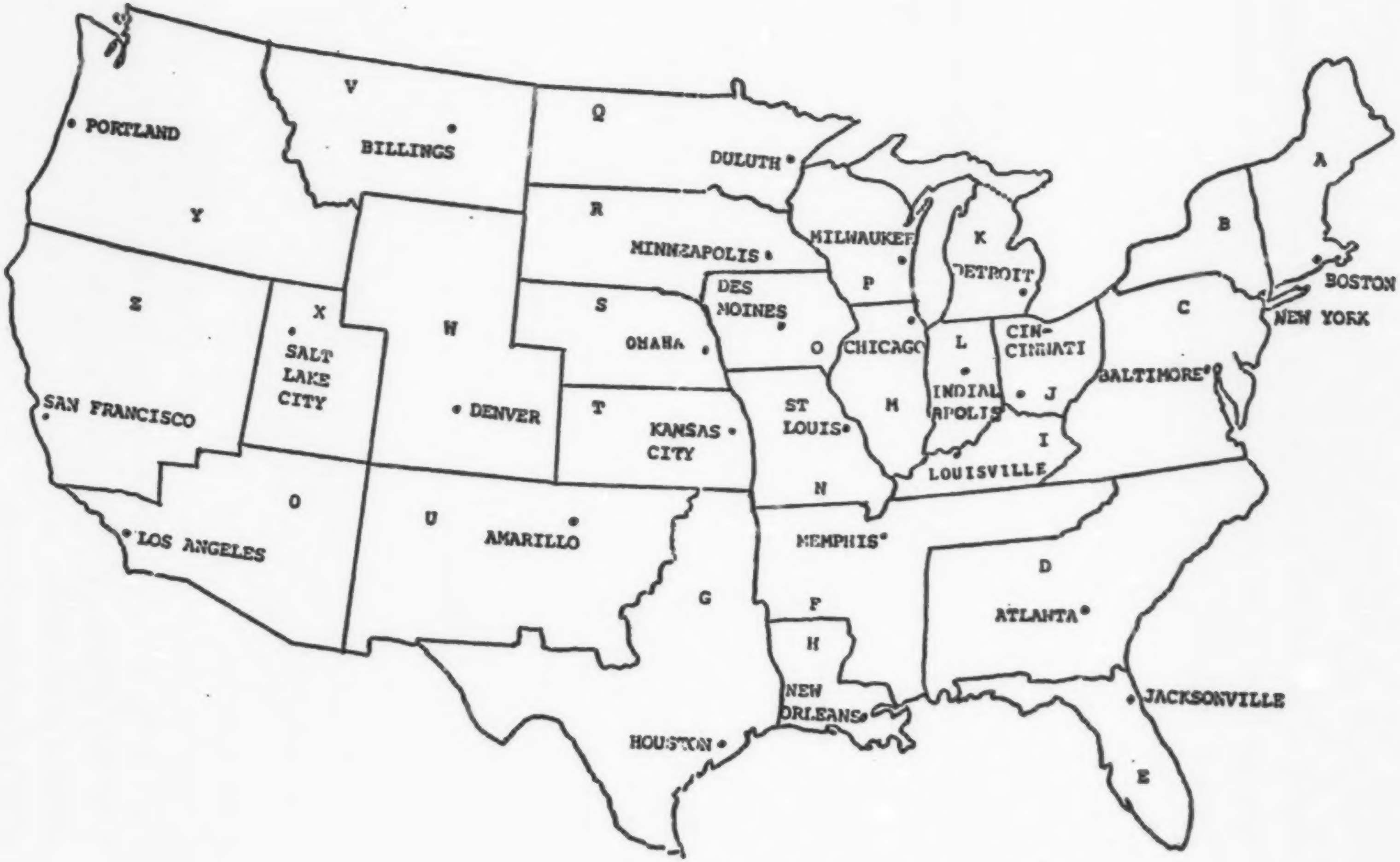
For most of the country, producing areas are defined in accordance with the APAT PAs. The Economic Research Service, USDA, defines the APAT production areas as those areas within which similar cropping conditions prevail. In most regions the producing areas also encompass one or more of the Census of Agriculture subregions or state parts of subregions. Where APAT producing areas exist, the PAs in this study are consistent with them. The only exception is the case where APAT producing areas cross state boundaries. In this instance the APAT PA has been partitioned into two or more PAs which conform to state lines.

Where budget data for APAT regions were not defined, crop production data and cost estimates were generated with the assistance of economists at the University of Illinois. Whole states for which this information was utilized include New York, Pennsylvania, New Jersey, Delaware, Maryland, Virginia, West Virginia, Florida, and Kentucky. Portions of other states in the South and Southwest are also partitioned according to the University of Illinois budget data.

A map of the producing areas is shown in Figure 1. The first letter of the producing area name denotes the consuming region to which the PA is assigned, and the second letter denotes one PA within that CR. For example, the state of Missouri has been designated as the consuming region N, within which are four

Figure 1

Consuming Regions



V
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PORTLAND
BILLINGS
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Y
R
MINNEAPOLIS
MILWAUKEE
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SALT LAKE CITY
OMAHA
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CHICAGO
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CIN-CINNATI
NEW YORK
SAN FRANCISCO
DENVER
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KANSAS CITY
ST LOUIS
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INDIANAPOLIS
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LOS ANGELES
AMARILLO
MEMPHIS
D
G
F
ATLANTA
H
NEW ORLEANS
JACKSONVILLE
HOUSTON
E

PAs: NA, NB, NC, and ND. Regions which are coded with a single letter are white areas where endogenous production is not defined. Western New Mexico, for instance, is signified by the consuming region name, U, followed by a blank for the producing area code.

Consuming Regions (CRs)

The United States is divided into 27 consuming regions. Each consuming region is composed of contiguous producing areas. In most cases, the CRs are whole states or are aggregates of whole states. State boundaries are not observed in those cases where commodity markets do not follow them. States split include Minnesota, Oklahoma, Texas, California, and Nevada. In every instance it was felt that each part of the state lies in a separate market area. For instance, the Duluth market (Q) is more likely to include North Dakota than it is Southern Minnesota, while South Dakota and Southern Minnesota are more closely related.

Each consuming region is oriented toward a major metropolitan area and/or transportation center. The basis for selecting the city is central place theory, which considers a city or region as occupying a position in an existing hierarchy of cities and regions. The central city in each consuming region is considered to be the city at the highset level within the region. Throughout this report the name of the central city is often used to signify the entire consuming region.

A map of the consuming regions is shown in Figure 2. The letters signifying the consuming regions range from A to 0, and the central city for each is designated on the map.

Major Regions (MRs)

Major regions are defined for reporting purposes only and are not functional in the model. The consuming regions are aggregated into seven major regions in the United States. The formation of seven MRs permits an overview of the effects of policy changes on principal sections of the country. A map of the major regions is shown in Figure 3.

Figure 2
Producing Regions

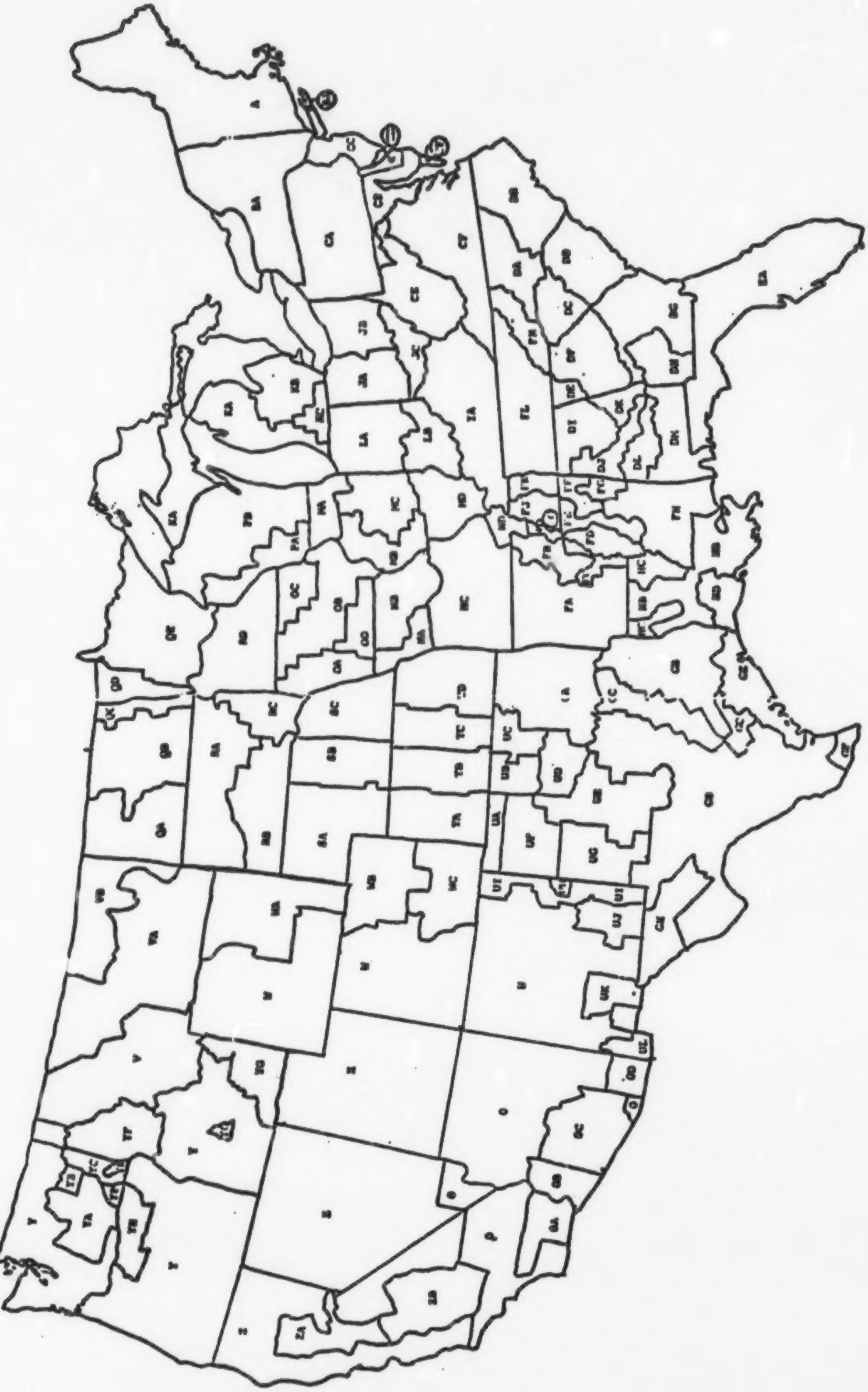
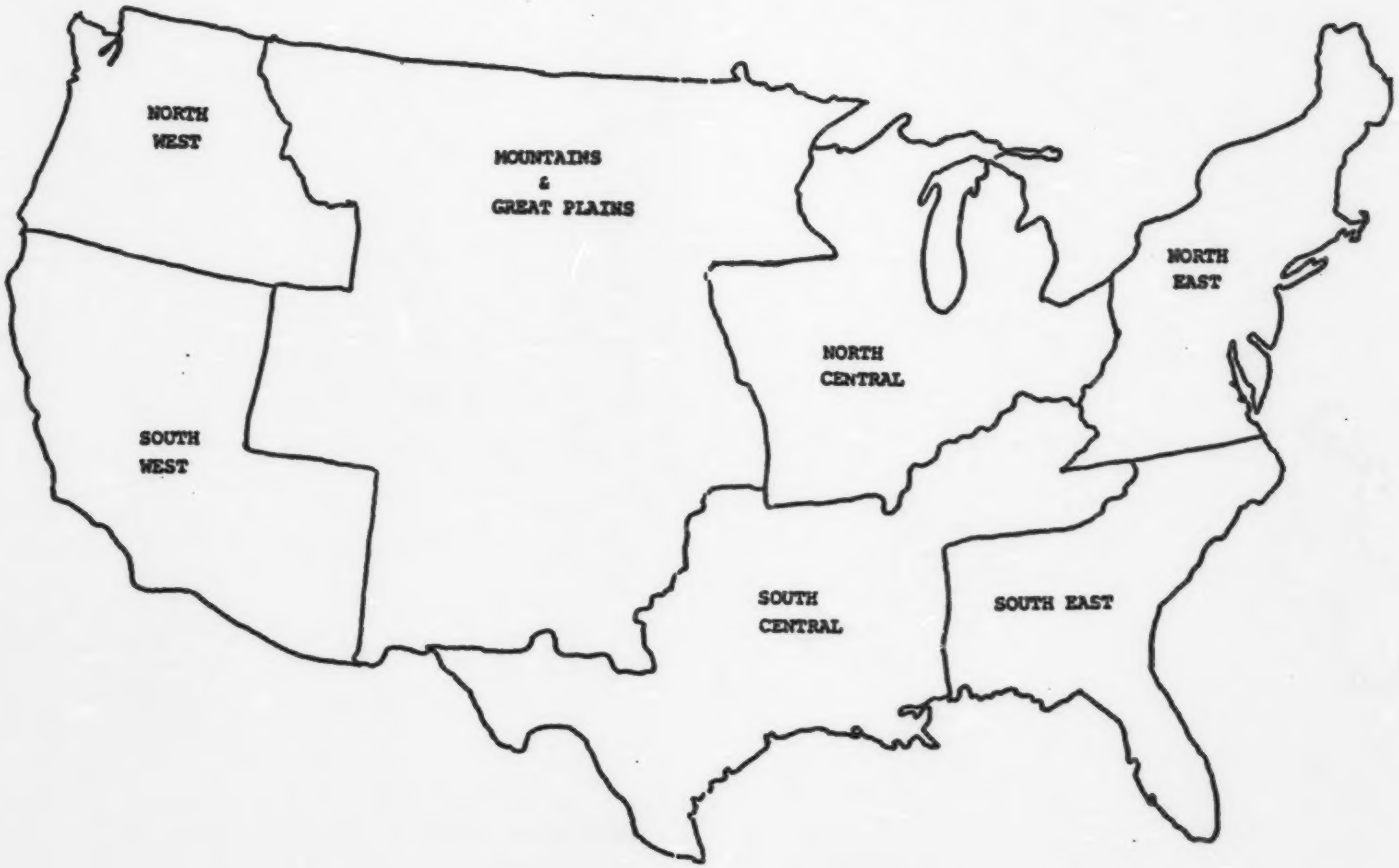


Figure 3
Major Regions


NORTH
WEST
MOUNTAINS
&
GREAT PLAINS
NORTH
EAST
NORTH
CENTRAL
SOUTH
WEST
SOUTH
CENTRAL
SOUTH EAST

Solution

The model is solved through a mathematical algorithm which simultaneously guarantees that 1) all regional demands are satisfied; 2) no regional resource constraints, e.g., disaggregated land base, are exceeded; and 3) the objective function is minimized. In so doing, the model solution depicts the land use and production pattern which satisfies all constraints at least cost.

An alternative construction would have been a profit maximization model which would provide a solution which maximizes returns to the agricultural sector. However, a unique characteristic of linear programming analysis guarantees that the dual solution of a cost minimization model is a profit maximizing solution; therefore, the activity levels for both cases are identical. The cost minimization formulation was chosen on the basis of modeling criteria which lend nothing to the accuracy or validity of the solution.

Pesticide Analysis - A Special Case of the General Agricultural Model

To be useful for pesticide policy analysis, the solution to the model must depict impacts within a short-run period (a 5-year time horizon). Due to the dynamics of pest control which include development of resistant pests and new technology, projections and simulations of impacts extending far into the future are futile. Therefore, the data base used in the LP model is constructed for a typical year in the 1975-1980 time period. This particular time frame provides an opportunity to analyze the short-run effects of pesticide policies. Unlike many other national models which have been constructed, the EPA model permits examination of immediate adjustments rather than the eventual long-run equilibrium position of agriculture.

An important criteria for a short-run model is that it generate solutions which are believable. The base model must closely coincide with current agricultural production (both crop mix and spatially) and current pesticide use patterns. However, the real world agricultural sector is not always optimal in the sense of "most efficient" allocation of resources to minimize or maximize an objective function. Therefore, the previously mentioned flexibility penalties were introduced into the model in an attempt to account for non-optimalities. Penalties are added to production cost as the acreage of any crop increses significantly over the historical trend. One purpose of these penalties is to reflect the cost of change — the implementation of new inputs, the change-over to new machinery, and risk aversion. Secondly, the flexibility penalties reflect the insensitivity of farmers to minor price incentives which otherwise might shift production patterns within the model. The benefits of using such penalties, which are unique to the EPA model, is that the model more accurately reflects the observed stability of the real world.

Application to the Substitute Chemical Program

Two formulations of the base model have been generated in support of the Substitute Chemical Program studies. The first was designed to evaluate the impact of cancelling the use of chlordane and heptachlor as soil insecticides for control of corn pests. The second application was in support of a study to evaluate the impacts of EPA's prior suspension of DDT on cotton. In the chlordane analysis, the model was solved for 1977 as a typical year in the 5-year time frame. For the DDT analysis, the base model solution depicted 1975 as typical of the 5-year period following changes in pesticide use.

Chlordane/Heptachlor Cancellation

To evaluate the impact of restricting the use of chlordane and heptachlor, the land base in corn-growing regions had to be disaggregated by insect infestation. Confidential data from a multi-client survey furnished by Doane Agricultural Services, Inc., was used internally within the model to generate "projected" regional infestations of cutworm , wireworm, and rootworm. The model's simulated distribution of infested acres is reported in Table 1. Infestations were further disaggregated by soil productivity class to enable interaction between the yields associated with various soils and crop loss due to infestations. Base model solutions for treated corn acreage (as opposed to infested crop acreage) are reported in Table 2. As Table 2 indicates, chlorinated hydrocarbon insecticides are the primary control agent on cutworm infested land while other insecticides in addition to chlorinated hydrocarbon insecticides are used to control rootworms and wireworms.

Table 1: Base Model Distribution of Infested Acreage by Insect Species

State	Insect Species		
	Wireworm	Rootworm	Cutworm
	million acres		
Ohio	0.19	0.51	0.43
Michigan	0	0.71	0
Indiana	0.34	1.43	0.46
Illinois	1.09	2.87	1.21
Missouri	0.32	0.57	0.59
Iowa	0.57	3.63	0.87
Wisconsin	0	1.09	0.34
North Dakota & Northern Minn.	0.01	0.19	0.02
South Dakota & Southern Minn.	0.40	1.82	0.45
Nebraska	0	4.06	0.19
Kansas	0.16	0.43	0.16
Total	3.08	17.31	4.72

Evaluation of the impact of restricting the use of C/H requires a system of comparative statistics in which the solution in the base model which allows C/H use is compared to the solution of a second model with C/H use options excluded from the feasible set of production activities. To accomplish this, several assumptions were required to define the parameters for specification of the second model.

In general, the parameters were chosen such that the model would depict a "worse case" impact associated with restrictive public action. The decision model an extreme case was made for the following reasons. First, the decision

Table 2: Base Model Distribution of Corn Acreage Infested by Wireworm, Rootworm, and Cutworm by Treatment Option

State	No Treatment	Other Pesticides	Chlorinated Hydrocarbon
	millions of acres		
Ohio			
Wireworm	0	0	.17
Rootworm	.03	0	.39
Cutworm	.12	0	.16
Total	.15	0	.72
Michigan			
Wireworm	.23	.13	.25
Rootworm	0	0	0
Cutworm	0	0	0
Total	.23	.13	.25
Indiana			
Wireworm	.05	.01	.28
Rootworm	.61	.07	.72
Cutworm	0	0	.36
Total	.66	.08	1.36
Illinois			
Wireworm	.1	.37	.49
Rootworm	.09	.93	1.0
Cutworm	.03	.03	.83
Total	.22	1.33	2.32
Missouri			
Wireworm	.03	.07	.11
Rootworm	.06	.18	.14
Cutworm	0	0	.45
Total	.09	.25	.70
Iowa			
Wireworm	.04	.26	.11
Rootworm	.01	2.33	.71
Cutworm	0	0	.54
Total	.05	2.59	1.36
Wisconsin			
Wireworm	0	0	0
Rootworm	.21	.77	0
Cutworm	.02	0	0
Total	.23	.77	0
Minnesota (N)			
Wireworm	0	.01	0
Rootworm	0	.08	0
Cutworm	0	0	.01
Total	0	.09	.01
Minnesota (S)			
Wireworm	.13	.13	.02
Rootworm	.11	1.15	.07
Cutworm	.23	0	.12
Total	.47	1.28	.21
Nebraska			
Wireworm	0	0	0
Rootworm	.16	2.26	.02
Cutworm	.06	0	.09
Total	.22	2.26	.11
Kansas			
Wireworm	.04	.05	0
Rootworm	.02	.21	0
Cutworm	.05	0	.04
Total	.11	.26	.04
Total	2.53	9.07	7.12

Table Note: Individual columns may not total due to rounding error.

makers who must weigh costs and benefits must be cognizant of the full range of potential impacts. If, in their weighing of costs and benefits they can determine that the costs associated with continued use exceed the derived benefits under maximum benefit conditions, the appropriate social strategy is more clearly defined. Data and evaluation which provide the spectrum of use-associated benefits under a "most likely" set of assumptions are also necessary to decision-making and will be provided after subsequent model solutions are generated. Secondly, a USDA sponsored study (Delvo, 1974) derived yield impacts associated with chlorinated hydrocarbon restrictions for the three endogenous insect species under several assumptions regarding alternative controls. As Delvo points out, the yield impacts are representative of "what might occur with a moderate to heavy insect infestation." A corollary set of assumptions for a typical year has not yet been fully specified. Therefore, the available data also played a role in making the choice to model the extreme situation first.

Explicit assumptions in the chlorinated hydrocarbon exclusion model included the areas treated with C/H during the base year (1977) and yield impacts associated with C/H withdrawal. The assumption was made that following the recent aldrin/dieldrin suspension, C/H would fill the void created by other chlorinated hydrocarbon withdrawals. Therefore, the expected use of C/H could be simulated by examining the most recent estimates of total aldrin, dieldrin, chlordane, and heptachlor use. To the extent that other chemicals in addition to C/H fill the void created by restrictions in aldrin and dieldrin, the model over-estimates C/H use and therefore over-estimates derived benefits from C/H use (costs associated with cancellation). Yield inputs, with the exception of those associated with rootworm treatment, were assumed to be at the level reported by Delvo. Delvo did not specify yield impacts on rootworm treated land other than to assume "that corn yield would not change if alternative insecticides were used to replace aldrin for corn rootworm control" (p. 6). He further stated that "there is some indication, from Illinois data, that yields may increase if nonorganochlorine insecticides are substituted for aldrin in corn rootworm control" (p.6). Further examination of this issue by entomologists in the Criteria and Evaluation Division indicated that, due to widespread rootworm resistance to organochlorines, the increased yields associated with shifting from organochlorines to other pesticides may be significant and are not unique to Illinois. As a starting point, the parameters for rootworm damage in the restrictive model specify a 15 percent yield decline if no insecticides are used to replace chlorinated hydrocarbons on previously treated rootworm land, and an 8 percent yield decline if C/H is used in place of other pesticides. In other words, it was assumed that the use of other pesticides would produce the average projected state yields while the use of C/H would lead to 8 percent yield declines on rootworm infested acreage. The full yield file is reported in Table 3.

Table 3: Impact of Restriction in Chlorinated Hydrocarbon Insecticide Use by Species

State	Species:	Cutworm		Wireworm		Rootworm	
	option:	w/ alt.	w/o alt.	w/ alt.	w/o alt.	w/ alt.	w/o alt.
		---------percent change from state yield---------					
Ohio		-5	-10	0	-10	0	-15
Indiana		-10	-25	0	-10	0	-15
Illinois		-10	-25	0	-10	0	-15
Iowa		-10	-25	-8	-12	0	-15
Missouri		-15	-30	-8	-12	0	-15
Lake States & Northern Plains		-10	-25	-8	-12	0	-15

Solution Impacts

No attempt will be made in this section to report the entire range of impacts associated with a C/H restriction as set forth under the preceding assumptions. To do so would be overburdensome and inconsistent with the intent of this paper.

Rather, the primary impacts will be reported. It should be pointed out that while impacts will be reported here on an aggregative basis, e.g., acres of corn per state or regions, the model solution shows impact by soil type within a region, irrigated, nonirrigated, or fallowed.

On a national basis, the model solution shows an aggregate increase in planted corn acreage of 200,000 acres. This results from the fact that corn, even at slightly reduced yields, is still a more desirable feedstuff than alternative feedgrains in many areas and that farmers would increase their plantings slightly to offset minor yield reductions. Total changes in land use are reported in Table 4. Slack or idle cropland (reported in the last column of Table 4) is reduced by 1,160,000 acres. This means that in total, 1.16 million acres more cropland would be in production following a C/H restriction in 1977 than would be used if C/H remains available. Again, the logic associated with this outcome is found in the farmers' willingness to plant slightly more acres of feedgrains in general to replace corn in particular. This change amounts to approximately a 3.7 percent reduction in slack or idle land between the two solutions.

As a welfare concept, the model reports total returns to land (net of variable operating expenses). In general, economic theory would suggest that actions which tend to constrain the agricultural sector (with an overall inelastic demand for agricultural products) will lead to price increases which more than offset the income effects of decreased production. The overall impact is higher total returns and higher aggregate profits. The results of the comparative models are entirely consistent with this theory.

As shown in Table 5, the net returns to land for all endogenous production activities in all regions increase by slightly more than $71 million. The regional distribution of this increase varies by region and production alternative, but on a national level the directional changes are unambiguously positive. The only negative entries in the U.S. total column of Table 5 are for chlorinated hydrocarbon, corn activities. These entries are negative, signifying the reduced returns to land

Table 4: Base Model Distribution of Infested Acreage by Insect Species

Region	Barley	Corn	Cotton	Soybeans	Oats	Sorghum	Wheat	Slack
	millions of acres							
North East	0.00	0.01		0.00	0.00	•	0.00	•
South East	0.00	0.39	0.01	-0.26	•	•	0.01	-0.14
North Central	0.16	-1.49	•	1.04	-0.01	0.09	-0.07	0.29
South Central	•	0.20	0.00	-0.01	•	0.23	0.01	-0.43
MIN. & GT. PL.	0.01	1.07	0.07	-1.16	0.26	0.07	0.50	-0.85
North West	•	0.01			•		•	-0.03
South West	0.00	0.00	•		•		0.00	•
U. S.	0.17	0.20	0.08	-0.40	0.25	0.40	0.45	-1.16

0.00 = less than 5,000 acres
• = zero
No entry = nonactive production alternative
Columns may not total to U.S. total due to slight rounding errors

Table 5: Changes in Net Returns to Land Resulting from C/H Restriction on Corn by Production Alternative, Aggregate United States Subregions, 1977

Production Activity / Region	North East	South East	North Central	South Central	Mtn. & Gt. Plns.	North West	South West	U.S. Total
	-----millions of dollars-----							
Barley, Dryland	0.14	0.01	1.49	0.08	0.68	0.02	0.01	2.43
Barley, Dryland, Fallow				.	1.55	0.13		1.70
Barley, Irrigated				.	0.83	0.10	-0.00	0.93
Corn, Dryland	2.29	1.05	1.02	0.05				4.40
Corn, Irrigated					6.88	1.68	4.96	13.52
Corn, Dryland, No Pesticides			79.44		19.68			99.12
Corn, Dryland, Other Pesticides			6.37		0.41			6.78
Corn, Dryland, C/H			-133.40		-4.40			-137.80
Corn, Irrig., No Pesticides					2.61			2.61
Corn, Irrig., Other Pesticides					12.30			12.30
Corn, Irrig., C/H					-7.29			-7.29
Cotton, Dryland	-0.00	.	2.91	0.79				3.70
Cotton, Irrig.			-2.90	4.31			0.84	2.25
Soybeans, Dryland	-0.01	1.53	46.99	0.01	-10.42			38.10
Soybeans, Irrig.					.			.
Oats, Dryland	0.07	.	0.01	0.00	5.36	.		5.44
Oats, Dryland, Fallow				.	1.41	0.00	.	1.41
Oats, Irrig.					0.03		.	0.03
Sorghum, Dryland	0.00	.	1.67	1.98	4.24			7.89
Sorghum, Irrig.				3.90	-0.90		0.17	3.17
Wheat, Dryalnd	0.37	0.09	-3.45	0.37	2.40	1.25		1.04
Wheat, Dryland, Fallow				.	7.72	0.59	0.08	8.39
Wheat, Irrig.					0.58	-0.78	1.34	1.14
Total Value	2.87	2.67	0.15	6.38	48.80	2.98	7.40	71.25
Ave. Shadow Price, $/acre	0.51	0.29	0.08	0.17	0.35	0.26	2.42	0.24

Table Notes: 0.00 = changes of less than $5,000
. = no change

from these activities after cancellation or alternatively, the returns which these activities generated prior to cancellation. On a percentage basis, the C/H cancellation results in increased return to corn production in the corn belt ranging from 4.4 percent to 23.4 percent and an overall 2.15 percent increase in returns to land in general (U.S. total).

Any modification of parameters such as yield per acre (as was assumed to be true with a C/H restriction) causes prior model solutions to be non-optimal. Activity levels in prior solutions no longer represent least cost solutions and the model will therefore "search" for new activities which can reduce the overall objective function. Activity adjustments can take the form of levels of production (acres within a region), transportation between regions, substitution of production between land classes (use of higher- or lower- yielding land within a production region), and/or substitution of one commodity for another in optimum feed mixes. All of these adjustments will lead to changes in total production within a region. Therefore, an examination of changes in production of the endogenous crops within regions provides both an intuitive feel for the severity of the impact as well as the overall level of the impact.

At the national level, the overall impact of the C/H restriction caused the following relative adjustments in the production of the endogenous crops: barley (+2.43 percent), corn grain (+0.70 percent), cotton lint (+0.02 percent), soybeans (-0.09 percent), oats (+3.90 percent), sorghum (+1.90 percent), and wheat (+2.43 percent). The absolute and relative changes for these crops are reported in Table 6 for seven aggregate subregions of the United States. As expected, the largest adjustments occur in the North Central and the Mountain and Great Plains regions where corn is the predominant feedgrain. The largest single adjustment is a reduction in corn production of 194 million bushels in the North Central region (6 percent of that region's base model production). Clearly, this represents a major change in production patterns and would result in major adjustments in

Table 6: Absolute and Relative Change in Production of Endogeneous Crops as a Result of C/H Restriction, by Aggregate United States Subregions, 1977

Region	Commodity						
	Barley bu.	Corn Grain bu.	Cotton Lint Bales	Soy-beans bu.	Oats bu.	Sorghum grain bu.	Wheat bu.
	millions of units (%)						
North East	*	0.56 (0.18)	0	-0.04 (-0.28)	0.04 (1.07)	*	*
South East	0.09 (8.12)	23.80 (12.63)	0.01 (6.39)	-6.04 (-5.15)	0	*	0.09 (8.12)
North Central	7.90 (44.85)	-194.28 (- 6.00)	0	38.60 (3.21)	-1.01 (-2.90)	7.83 (11.48)	7.90 (44.85)
South Central	0	15.69 (88.61)	-0.05 (-0.93)	-0.62 (-0.27)	0	15.13 (7.18)	0
MTN & GT. PLNS.	0.65 (0.25)	115.68 (8.78)	0.03 (0.54)	-33.62 (-11.09)	12.64 (4.88)	-2.42 (-0.31)	0.65 (0.25)
North West	*	1.19 (6.14)	0	*	0	0	*
South West	-0.08 (-3.07)	0.44 (0.24)	0	*	*	0	-0.08 (-3.07)
U.S. Total	8.56 (2.43)	-36.91 (- 0.70)	*	-1.71 (-0.09)	11.61 (3.90)	20.55 (1.90)	8.56 (2.43)

* = Less than 5,000 units

land use. From Table 4 it can be seen that most of the equilibrium adjustments occur by substituting soybean production for corn production (1.04 million acre increase in soybeans for a 1.49 million acre decrease in corn). In addition, 160,000 additional acres of barley and 90,000 additional acres of grain sorghum are produced. After all adjustments in the land base of the North Central region have occurred, 140,000 additional acres of cropland are brought into production. Income adjustments associated with these adjustments are depicted in the "North Central" column of Table 5 and result in an increase in net returns to land of $150,000 in aggregate.

Further adjustments which occur in the North Central region (although not reported completely in this section) show an increase in interregional transportation of corn into the North Central from other regions of the United States equalling 171 million bushels. As a result, although gross production of corn in the region is reduced by 194 million bushels, feeding of corn to meet livestock demands within the region is reduced by only 22 million bushels. Sorghum grain is the main substitute feedgrain and is increased by 24 million bushels. Sixteen million of this 24 million bushel increase in sorghum feeding is supplied via interregional trade.

In general, while examination of any one region, commodity, or parameter in the model might suggest major adjustments and/or impacts associated with the C/H restriction, the overall evaluation of the national model suggests minor adjustments which the agricultural sector can respond to. In addition, it must be kept in mind that these solutions depict the consequences of a C/H restriction assuming extreme impacts. Further, these adjustments are depicted as instantaneous. In reality, the impacts, should C/H be suspended, will be spread over several growing periods as growers foresee and anticipate the suspension and supplies of C/H are gradually depleted. The more gradual nature of a realistc restriction would cushion the adjustment process.

DDT Cancellation on Cotton

Several modifications of the LP model were made in order to facilitate the evaluation of economic impacts caused by the cancellation of DDT use on cotton. First, all parameters in the model which are time specific were adjusted to represent 1975, the year for which the cancellation was evaluated. Secondly, the land base in the model was collapsed from nine land classes to an aggregation of three land classes. This was done in an effort to reduce the cost of model solution and to evaluate the sensitivity of the model to a less specific land base. Third, new crop yield coefficients were generated to represent the new time horizon and the aggregated land base. Fourth, a new method of generating flexibility penalties was developed based on statistical variability of observed crop acreages over 25 years. The system was tested and included in the model based on its improved performance. Fifth, cotton demand was defined on a consuming region basis and appropriate transportation vectors were defined to allow for interregional cotton trade. This had not been accounted for in the feedgrain model.

The Base Model

The LP model constrained the maximum production of cotton using DDT and using no pesticides to be no greater than the proportions shown in Table 7. The regions referred to are:

2 - Georgia, Carolinas, Virginia;
3 - Texas, Oklahoma;
4 - Kentucky, Tennessee, Alabama, Arkansas, Mississippi, Louisiana;
5 - Missouri; and
6 - California, Arizona, New Mexico.

As Table 7 shows, only regions 2 and 4 utilized DDT in any significant proportion.

Two benefits have been reported to accrue to the use of DDT — decreased costs and increased efficacy. Although there is controversy on this issue, the increased efficacy has not been demonstrated and we have assumed that it is not true. It is clearly true, however, that DDT costs less than alternative insecticides. Table 7 shows the assumed costs of insecticide (including application) when DDT is allowed and when it is not.

Table 7: Historic Cotton Insecticide Use

Doane Region	Insecticide Cost DDT $/acre	Insecticide Cost Other $/acre	Proportion Treated DDT %	Proportion Treated Any %
2	48.53	59.60	30.00	93.1
3	-	15.03	-	27.2
4	24.47	27.05	26.9	79.0
5	-	6.19	-	28.0
6	-	12.38	-	72.4

In the LP model three distinct cotton production activities were defined on each land class in each producing area:

1. Cotton with DDT (constrained to be less than the proportion of total cotton shown in Table 7)
2. Cotton with other insecticides
3. Cotton with no insecticides (constrained to be less than the proportion receiving none as shown in Table 7)

The DDT cancellation on cotton was evaluated by solving the linear programming model for equilibrium land use allocation when DDT is available and, alternatively, when DDT is not available. Both solutions are based on the year 1975. The results of these two solutions can be summarized in acreage shifts, costs of production, and economic returns to land (a proxy for profit).

The cancellation of DDT caused a slight reduction in total cotton acreage in the United States as evaluated within the framework of the linear programming model (from 10.972 million acres to 10.952 million acres). The reduction in acres was distributed as follows: Atlanta, -3,924 acres (-0.42percent);

Memphis, -8,915 acres (-0.37 percent); New Orleans, -24,056 acres (-7.21 percent); Louisville, -6.25 acres (-34.05 percent); San Francisco, +17,590 acres (2.24 percent). The relatively minor shifts in acreage demonstrate that the change in production costs associated with cancellation is not large enough to generate significant changes in comparative advantage among regions, and therefore does not affect cropping patterns for cotton or alternative crops.

Aggregate costs of cotton production were affected both by a change in production costs per acre in some regions and by the slight changes in acres planted between regions. In the Atlanta region, aggregate production costs increased by $2.1 million (1.4 percent); in Memphis, the increase was $1.8 million (0.5 percent); in New Orleans, where cotton acreage decreased the most, total production costs declined by $3.0 million (-6.45 percent); in San Francisco, the increased plantings led to increased production costs of $4.3 million (2.2 percent). Total U.S. production costs increased by $5.2 million (0.4 percent as a result of the cancellation.

Returns to land, which serve as a proxy measure for impact on the profitability of cotton production, were affected slightly. In the Atlanta region, these returns decreased by 0.37 percent (from $45.35 million to $45.19 million); in Memphis, the decline accounted for a 1.93 percent reduction in the precancellation returns of $63.53 million; and in New Orleans the $100,000 reduction in returns accounted for for 0.93 percent. San Francisco encountered an increase in returns to land of 0.26 percent (from $33.41 million to $33.50 million).

The analysis which was carried out through comparative analysis of linear programming solutions indicates that production cost increases due to the DDT cancellation on cotton are of insufficient magnitude to cause sizable shifts in economic parameters at the regional or national levels, e.g., acreage, production, total costs, and returns to land.

MATHEMATICAL LINEAR PROGRAMMING

Stanley Hargrove*

When I saw the title of this presentation and then heard Fred Arnold say, "We built a linear programming model of U. S. agriculture," it occurred to me that that's a phrase that we've thrown around for 5 or 6 years now. It sounds a bit pretentious to people who don't know what it is. We don't have all of agriculture in the computer — though next week I hope to; we are still working on that.

Really, we are only talking about the major field crops. Even though a lot of the other crops like fruits and vegetables, nuts, orchards, and all those kinds of things are extremely important to the economy, particularly the economy of certain regions, and the use of pesticides is very critical to them, we're not talking about those. We're just talking about the major uses of land, the major field crops, and the part of agriculture that people think of when they talk about farmers.

Fred is exactly right. I'm going to try to tell you how I view mathematical programming, so that you may understand, when he gives the results, all those numbers and what they mean, because he can't say it after every number, and it gets a little boring that way.

The social costs of pesticide use are generally described in terms of human health costs or degradation of the environment, and, as Fred has said, they're not economic. However, the benefits of agriculture pesticide use are generally economic in nature. That is, they contribute to the economic well-being of the public. Pesticides have been an important part of the dramatic increases in agricultural productivity over the last several decades. However, little good

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evidence has been presented to measure the overall contribution of agricultural pesticides — that is, total pesticide use. Without such measurement, we're left with no reliable basis for evaluating the total impacts of pesticide restrictions. If a good measure could be found, then productivity impacts could be traced through the market mechanism to estimate changes in consumer prices and farmers' incomes. You see, however, that's just pesticides in the aggregate, and evaluating those is interesting, but of little value to policy makers.

It's a well-founded basis of the Substitute Chemical Program that certain pesticides cause far greater environmental damage than others, but the others can be substituted for them in use. The substitution may be more expensive and/or less efficacious, and then some decline in economic efficiency can result from a substitution. However, the existence, or potential existence, of good substitutes holds out the possibility that substantial environmental damage can be avoided at acceptable costs to the consumer and to the farmer in terms of productivity.

So, our purpose here is to identify the economic costs borne by farmers and by the public at large when specific pesticides are withdrawn from specified agricultural uses. In order to do this we must consider the likelihood that the substitute chemicals will be adopted. Further, we must consider other likely courses of action on the part of farmers and evaluate the aggregate economic results of those actions.

So, let's examine a typical farmer; I won't give him a name. What choices does he have when an old reliable pesticide is disallowed? Well, typically, a farmer has numerous kinds of alternatives. First, he can attempt to maintain his yield by utilizing a substitute pesticide or by utilizing other means of pest control. Second, he may just accept the decline in crop yields and go on; this may well be a good alternative if the decline in yields is small, because, after all, he loses the cost of the pesticide. Three, he may reduce or eliminate the acreage of that crop and substitute some other crop for it, or, four, he may reduce or eliminate that crop and just let the land lay idle. Whichever alternative he chooses, our farmer will be financially worse off — at least he won't be better off — because if one of those alternatives represented an improvement for him, he would have been using it in the first place.

Thus, whatever the alternatives in any given situation, the removal of an important pesticide is likely to increase production costs for the farmer who had been using it. Can we, then, conclude that these costs will result in economic damage to both farmers and consumers? Maybe, but not necessarily. Let's trace it through. The first growing season after a restriction, the total production should be down, and, therefore, unit costs will be up. Now, as the crop is marketed, the price of the crop will be bid up in the face of potential shortages. We all know what happens to food prices when consumers think there's a shortage.

In subsequent growing seasons, all the farmers, not just the ones who have been using the pesticides, are likely to respond to the initially higher prices by increasing their production. This will, in turn, bring prices back down. In the normal course of events, price and production will finally stabilize at a somewhat higher price and lower production than before the restriction.

As I've illustrated it here, the kinds of responses (the interactions) are apparent and they're intuitive and they're simplistic. However, the determination of which choices will actually be made and the measurement of the interactions and the results of those is a complex and enormous task. Although there is a nearly infinite number of special sophistications of the relationships, the obvious ones are sufficient to gain an understanding of the problem and to prepare realistic estimates of the processes. Thus, our task is not to build a complex model, but to build a simple one which will have the capacity to simultaneously consider all the important choices and interactions. It's the sheer size that has made this task impossible before.

Our approach to modeling the agricultural sector of the United States was to first reduce the number of individual choices and relationships to some finite and manageable number through abstraction and generalization, then to represent each alternative choice and the relationships between them as mathematical functions. Finally, we utilized the power and the speed of a large-scale computer to consider all of them simultaneously.

The first step in the reduction of choices was accomplished by identifying a typical farm in each of several regions of the contiguous 48 states. Thus, the number of farms was reduced from several million to only 129, with little loss in aggregate analytic accuracy.

In order to legitimately define such farms, our regions were consistent with those identified by the old Aggregate Production Analysis Team, which we will refer to as APAT, of the Economic Research Service, USDA, as being homogeneous in production.

A further step in the reduction was to identify only seven major crops for consideration. First, of course, corn and cotton were chosen, since they were the subjects of the analysis. Then we chose barley, oats, sorghum, soybeans, and wheat, since they either compete with corn and cotton for land or they substitute for corn and cottonseed as feed and food.

Within each region, the thousands of possible land types were aggregated into a small number of land groups with similar characteristics. Farm inputs were aggregated into only two classes: land, measured in area, and other inputs, measured in dollars. The agricultural products produced by all these activities were limited to the consideration of only the grains barley, corn, oats, sorghum, and wheat; oil meals — soybean and cottonseed; and cotton lint. Their values as feedstuffs are represented simply by protein and TDN.

Agricultural markets are represented in a few large consuming regions represented by fixed quantities demanded. Between each pair of consuming regions, only one transportation possibility for each commodity was considered, so we've cut it down a lot and what used to be millions of things is now a few thousand.

The interrelationships between production choices were represented by two requirements. First, the total production plus imports in a region must at least equal the demands in that region. The relationships between land uses were represented by the limitation that no more land could be used than was available. The profitability of each choice was represented as the negative of the cost, the non-land cost, of inputs of each activity. The goal was to minimize the total cost of production and transportation.

Now, for anybody who is interested, we could go through mathematical proof that that does, in fact, represent market equilibrium, but I don't think you really want to hear that today.

The mathematical tool which could consider all these choices and relationships simultaneously is a special kind of activity analysis called Linear Programming; I'll call it LP because that's easier. In LP, each alternative or activity is a mathematical variable which can range in value from zero to infinity. The land restrictions are represented as mathematical relations, equating the sums of use to the availabilities, and one of the possible uses is "non-use," or disposal. The demand requirements are represented as mathematical relations equating the sums of productions with the sums of uses. Again, a use here is disposal. The profit maximizing behavioral assumption was represented by minimizing the sum of the production and transportation costs.

When such a model is "solved," the methods and acreages of each crop in each region are determined, as are the marginal values which proxy for market prices, the market values of each commodity and each land group in each region. Thus, both farm incomes and consumer prices are addressed by the model.

As the model is now constructed, the model solutions approach the equilibrium, or the final stable results. Thus, the direction and perhaps the ultimate values of economic variables can be projected, but the year to year adjustment process and dynamic costs and benefits are largely ignored. The economic impacts of a pesticide restriction are then determined by comparing the economic variables from two solutions, one solution which allowed activities utilizing the pesticide and one solution which did not allow them.

So we have a model, and it has a unique capability among all kinds of models that I know about to talk about the substitutions of pesticides for the crop about the substitution of crops for each other, and to talk about the impacts of one region's decisions on another region and, finally, on the consumers and the farmers in aggregate.

That's the end of what I have to say. I feel like I have not said very much, but I hope this is, in fact, an intuitive basis, so that you'll have kind of a feeling for the numbers that come out of it.

Fred now has gobs and gobs of numbers for you. And I have to say that one of our tasks in solving this is trying to distill, from all those reams of computer output, what the appropriate numbers are, what they mean, and how they impact society.

INTEGRATED PEST MANAGEMENT

Dr. Kenneth J. Hood*

I was asked to give an overview on the Alternative Methods of Pest Control, or our integrated pest management program, and at first I was a little surprised because we really don't deal with substitute chemicals and the funding comes from a different program element. But there is a commonality of purpose between the Substitute Chemical Program and the Alternative Methods of Pest Control as each seeks control methods which reduce environmental burdens of pesticide residues and unwanted effects on non-target organisms.

I manage the program on a grant and interagency agreement basis. We have no active EPA laboratory program. Our largest single effort is an interagency program operated under the auspices of the National Science Foundation.

The program was originated in about 1970 by a group of scientists called together by Dr. Carl Huffaker of the University of California at Berkeley. These people were looking for a different approach to controlling insects in crops, and after much discussion a proposal was prepared which called for the efforts of hundreds of workers and millions of dollars. They came to Washington looking for Government support.

The proposal was circulated through several agencies in the Government and the authors were told it was too large. Therefore, they reduced the proposal, producing a program called "The Principles, Strategies and Tactics of Pest Population Regulation and Control in Major Crop Ecosystems." The program was subsequently funded by three agencies: USDA, EPA, and the National Science Foundation. The work is now in its third year and is scheduled to run for 5 years. The cost is about $2 million per year. Later EPA also funded a large grant to the University of Missouri to work on the corn and vegetable ecosystems.

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Still later we initiated grants in several areas which dealt with some specific methods of insect control, namely viruses, juvenile hormones, and pheromones. I would like to discuss a little more of the program sponsored by the interagency agreement since the major effort.

In the interagency agreement work we deal with six crop systems: cotton, soybean, alfalfa, pine, citrus, and the stone fruits. The program as it is now structured encompasses the efforts of 19 land grant schools. Each school is located in the particular crop area in which its research interests lie. There are some 387 scientists on this program including full- and part-time workers. The other major grant program at the University of Missouri works on the corn and vegetable ecosystems and primarily on soil insects in these systems. It supports about 101 scientists. If you include the other smaller grants we support, the total manpower amounts to about 500 people on the entire extramural effort.

Some of the strategies and tactics being explored in the California program are based upon insect population dynamics and interactions of those populations, particulary through the entire growing season. It was felt that we didn't have a good knowledge of where the insects were throughout the season and particularly of the relationship of their lifecycles to the presence or absence of the crop they were attacking. We also needed to know more about their relationships with predacious insects.

We are examining a number of areas depending upon the crop, so this account will only catalogue some of the control systems that are being studied.

First, there is work in the genetic resistance to insects and disease. This was ongoing work already under way in the cotton crop, so we are continuing that effort.

The use of parasites and predators, with interest in both imported insect parasites and predators is another area of interest. We know that a catalogue of the world's successful use of these insects amounts to some 70 very successful situations in which predators have controlled the undesirable insects and some 250 instances in which partial success was achieved.

There may be a problem in introducing foreign predators into a domestic crop ecosystem, if they are so successful that the domestic predators decline to the point at which the entire insect ecosystem is unbalanced. Considerable caution is needed to achieve success with this approach as results may not be easily predicted for a number of reasons.

The use of insect pathogens is also being supported. We have a small effort in that area.

Another strategy of interest is the exploration of better cropping and habitat modification methods, which may include conventional operations such as crop rotation, the use of early maturing varieties to push the crop maturity ahead of development of the particular insect pest, and alternate host destruction.

There is some research on use of non-selective chemicals to get selective results. We have not discounted the use of pesticides. They are important but effort is being made to use them more efficiently. For instance, the use of trap crops may be helpful. Trap crop rows where insects congregate because of better food supply permit their concentration and facilitate their destruction by conventional means.

We are also investigating the use of attractants and repellents in the pest and in the host plants. We have found that a little bit of damage on some of the crops turns out to be good because the crops are then stimulated to grow. Alfalfa is a good case. A small amount of insect damage may not be harmful; the plants simply grow faster. It is unfortunate that we cannot regulate the amount of insect injury to benefit from this observation. On the other hand, this phenomenon demonstrates that the plants do have a useful response which may be economically beneficial to the farmer.

We are doing research on the biochemical aspects such as hormones. For instance, kairomones are beginning to receive attention. These compounds provide the stimulus which attracts the predators to the prey and therefore may play an important role in development of control methods.

The above is a general overview of our effort. Of course, each crop ecosystem receives a different emphasis according to its needs. We try to match the crop system, the insect problem, and whatever control seems to fit the situation. As you know, pesticide use varies. For instance, the cotton crop uses a lot of pesticides while the citrus crop, for which prey-predator relationships have been enhanced, uses a minimum of pesticides.

There are four program expectations that have been developed. The first is that we expect to establish guidelines to discern when there is a real need for pesticides use. Another program expectation is the discovery, characterization, and use of new agents in pest conrtol: This includes such items as resistant crop varieties, insect parasites, and insect pathogens. Last year we examined 33 new parasites; this year the number is up to about 80. Another expectation is development of a protocol to explore the cause of insect over-abundance. Elimination of insects is not possible, of course, but the reasons that the populations become uncontrollable and do enormous damage need research attention. The fourth expectation is to try to place pest control on a scientific and factual basis as much as possible, so the farmer can manage pests in a more realistic way.

Regarding the grant work in the other crop ecosystems, in the corn and vegetable ecosystems the emphasis is confined to soil insects. The study covers most of the corn belt. Cutworms, wireworms, white grubs, maggots, and slugs are the main problems, with the biggest emphasis on cutworm and wireworm.

As you know, one of the most difficult problems in the case of soil arthropods is prediction of exactly where these populations can be found. We have some very good control chemicals which are not going to be available in the future. Therefore, to localize treatment with other chemicals we need to know where to find the insect pest populations. In our study we have standardized methods of insect collection and methods of evaluation to permit exchange of accurate information among the scientists working in several states. Although the work is incomplete, within the next 2 years we hope to characterize the habitat of the soil insects and to predict their location with some accuracy.

In another program, started this year at Michigan State University, we are studying the role of weather in development of insect populations. We hope to utilize weather information in prediction of where some specific insect populations may be found. This program was previously funded by the National Science Foundation. We are continuing, with some modifications, the excellent early work.

Lastly, we are working on urban pests, that is, those insects found around the home. The objective is to reduce the amount of pesticides used in the home and reduce the hazards of accidental contact with the pesticide chemicals. Therefore, we are supporting a small program on control of cockroaches. Essentially it is a habitat modification study. The work was previously supported by Texas. Indeed, they still contribute substantially to the work.

DR. ZWEIG: How do you distribute your reports, are they available to others, and what is the actual output of the program? Have any of these things been tried out in the field and are they being used by farmers all over the country, or what is the end result of this integrated pest control program?

DR. HOOD: Most of the 500 people are in experimental stations or related with schools of agriculture, and they all have a very great sense of pragmatism. In other words, their first criterion is that the concept is useful and considered in terms of actual field practice. They are doing field work.

In the case of citrus they are working mostly with commercial groves, so you might say that anything that's coming out of this study is already going into the field and is strongly field tested. This even includes the cockroach study as we are working with several commercial exterminators in that case.

I believe that the results in this particular case are probably getting out into the field really ahead of receipt of formal reports in some cases. In terms of reporting aspects, we have annual reports but these are, of course, interim annual reports. The reports are available and the final project report will be widely disseminated.

As far as conclusions go I must point out that nearly all these programs are in the middle of the work, so you can't really get the full conclusions at this particular point. Now in terms of information to the Office of Pesticide Programs, which I feel is the great consumer for these results in terms of the Agency use, last year I sponsored a series of seminars in which each of the crop ecosystem leaders came in and reported directly to a group of people from the Office of Pesticide Programs on his crop. Those seminars will probably be reinstituted again now that we've gone through another growing season, and you'll be hearing from me. That is the way the information is handled. There will be, of course, final written reports.

DR.. ZWEIG: It certainly is very good news that what the Office of Research and Development does is being placed before the Office of Pesticide Programs, which might be the eventual user of the information. We'd like to have a lot of this type of interrelationship.

TOXICOLOGICAL METHODS AND GENETIC EFFECTS WORKSHOP SUMMARY

Dr. August Curley*

In the toxicological research progress session there were some 27 to 29 presentations so it will be quite impossible for me to review all those presentations to you, but what I will attempt to do is highlight some of the work, present some of the problem areas, and draw perhaps one conclusion from the studies that were presented.

The studies as reported in the toxicologial research progress session included both ongoing research and research that was recently initiated for the next fiscal year. These studies include an intramural effort and an extramural effort.

The extramural effort consists of contractual agreements, including interagency agreements outside of EPA. The studies include some basic studies. These basic studies were acute studies with subacute studies and some chronic studies with the chemicals that we call substitutes for those pesticides that have either been suspended, cancelled, or are under internal review or in litigation.

The special studies included some epidemiological studies and screening tests for for carcinogens, mutagens, and teratogens with emphasis on age and sensitivity periods, particularly for the pesticides that might be considered carcinogens.

Some of the new studies include behavioral studies, endocrine effects, cardiovascular effects, and possible immunological effects. A major part of the program included the use of model compounds for protocol development and pharmacokinetic modeling.

Some of the highlights in the research progress session included new data in the area of inhalation toxicology, which included pulmonary-hepatometabolic alterations of some of these compounds which may suggest enhanced toxicity due to these conversions via that route of exposure.

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Another highlight that was discussed during the session on carcinogenesis, mutagenesis, and teratogenesis was the use of an in vitro pre-screening technique to assess potential carcinogens. Another study which was reported indicated the development of epithelial cell cultures versus diploid fibroblasts for the evaluation of the possible mutagenic or carcinogenic effects of some of the substitute chemicals. A teratogenic study was reported, both anatomically and functionally, with one of the pesticides which might deserve some mention. Some teratogenic effects have been noted with cacodylic acid.

Inherent in any toxicological research are various problems that arise and some of these problems deserve mention. I'll mention only some of the details. One detail which might be considered is the vehicles that are used in dosing of the various animals.

Some of the vehicles might have a synergistic or potentiation effect and therefore a selection of vehicles for the administration of these compounds via various routes should be taken with precaution. The dosing regimen seems to be a problem, including dose studies for maximal tolerated doses in selected animal models.

One precautionary problem that might be considered is diseases that might be endemic in various animal models which might lead to false positive results. Another problem area is the selection or possible selection of sensitive species that are less expensive than more expensive animal models to evaluate selected effects prior to initiating studies in more expensive animals and of course, last but not least, is the selection of a compound as a pure material or as a technical material for the study, including techniques for the study of that compound in selected protocols.

In conclusion, for our session the emphasis has been on good science without prejudice to single out compounds or a compound or a manufacturer. The emphasis, of course, is to assist the Agency in making sound and responsible regulatory decisions regarding the safety of these compounds that are listed as substitutes for those compounds that have either been suspended, cancelled, in internal review, or under litigation.

ECOSYSTEMS/MODELING WORKSHOP SUMMARY

Dr. Norman R. Glass*

Basically I'll be telling you a little bit about the ecosystem/modeling program which we essentially broke out into three areas: First, the development of microcosms as a methodology or as a means of assessing potential substitute chemicals, the development of microcosms per se. Second, the evaluation and discussion of mathematical modeling techniques that relate to various aspects of the Program. Third, we had a presentation from some members of the Office of Pesticide Programs (OPP) on certain contract activities.

The microcosm methodology development was presented in three primary areas: first, the development and validation of the use of the technique in the terrestrial setting; second, the discussion and evaluation of fresh water microcosm developments; and third, the development and testing of a marine microcosm system.

Under the mathematical modeling efforts we had three primary areas of interest, including one unscheduled presentation by Dr. James Hill. The first are of interest in mathematical modeling dealt with the large-scale modeling program initiated by Michigan State, in which we were concerned with the application of a pesticide, the runoff of that pesticide from the land into water, and the subsequent movement, distribution, degradation, and fate and effects of that pesticide in a fresh water lake system.

Second, we were concerned with the mathematical simulation of a microcosm per se; that is, the use of a simulation model to evaluate the use of a terrestrial microcosm.

Third, the unscheduled presentation by Dr. Hill dealt with the use of mathematical analytical techniques whereby one can use mathematical modeling methods

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to essentially evaluate -- to do sensitivity analyses and describe functional relationships and topology of mathematical models.

We had considerable discussion during the course of the last day and a half on such things as how possible it is to generalize from one chemical to the next in terms of the potential impact or effects of a chemical on ecological systems. How broadly can we generalize? Do we have to deal with each chemical on an ad hoc basis? Are there some integrating or general principles that one might use in order to cut short some of the assessment time required to look at new chemicals? Also, we tried to ask and answer, although I don't think very successfully, the question of how little information decision makers or policy makers can successfully use in making their decisions.

Also, the question was raised and a response was given to the possibility of a periodical or a newsletter to deal with some of the research that's going on under the Substitute Chemical Program. The question was asked, shouldn't there be an abstract project or some way of notifying other investigators of work ongoing in the field. As a consequence, everyone gave to Carter Schuth of the Office of Toxic Substances a couple of sentences describing their activities, their names, and their addresses. Presumably she should be coming forth soon with some kind of mailing list and hopefully some information.

We also discussed the concept and utility of various types of indexes, both single factor and multidimensional indexes. Bioaccumulation, species diversity, and other types of indexes which might indicate the effect or movement or some other consequence of one of the substitute chemicals or any other chemical came under discussion.

I think, in general, it was a useful session in that it did acquaint the participants, at least in the ecological portion of this Program with some of the activities going on in OPP in some detail. Probably a number of Office of Research and Development activities were made better known to the Office of Pesticide Programs as well.

CHEMICAL METHODS WORKSHOP SUMMARY

Dr. E. O. Oswald*

The two days of sessions concerning chemical methodology may be subdivided into basically two areas. Speaking as chemists, we discussed the working tools, the varying complexities of instrumental detector systems, and what it takes to do a particular job as the complexities increase.

Furthermore, in addition to the working tools, we always have to take into consideration the techniques, limitations of the techniques, and general methodology as applied to man and his environment, determining in this case the presence, the quantity, and the type of material in environmental samples.

More specifically, in the area of instrumental detectors discussion was given to micro-electrolytic conductivity detector or the Hall detector; extension of multiresidue methodology; the limitations, complexities, and, furthermore, the magnitude of problems associated in evaluation of impurities associated with technical preparations; and the myriad of predicting and determining these problems.

Furthermore, there were areas of our discussion concerned with problems associated with reentry: methods of measuring pesticides, protecting the individual, and feasibility studies in this case to determine applicability of proposed methodology.

Beyond that, in the second day of sessions general discussion was given to new programs which were implemented in recent months. These covered the working tools or the instrumental detector systems required for doing specific jobs and analyses, upgrading techniques, problems and limitations on these techniques, the importance of specificity and its relationship to sensitivity of analytical techniques. We must always keep in mind that no one specific system solves everybody's problems.

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The complexity of biological substrates and the methodology as applied to these substrates varied from those of the human, including tissues, fluids, excretor, to those of plants, animals, air, water, and soil. As concluded with existing methodology and instrumental techniques, no one system again satisfies all the needs.

During these 2 days of sessions we all had a chance to look at the state of the situation and make comments. It was a very open session and one which had a quality which I would like to close on with a very brief description. This quality is one which I have admired in numerous persons for many years and very appropriately at this time, specifically in a person who has been a major driving force behind this Program, namely Dr. Leonard Axelrod.

This quality which this particular symposium exemplified is as follows: As scientists always take pains and exert maximum effort to do the best we can in designing experiments and interpreting the data. Most importantly, regardless of the outcome of the data, be honest with ourselves and our fellow man, but most of all, also keep in mind, don't be afraid to stand up for our individual convictions.

APPENDIX I

SUBSTITUTE CHEMICAL PROGRAM
THE FIRST YEAR OF PROGRESS

AGENDA

Wednesday, July 30, 1975

Registration

8:00 a.m. - 9:30 a.m.

Plenary Session

9:30 a.m.	Welcome Dr. William G. Roessler
9:40 a.m.	Introduction Mr. Kenneth O. Olsen
9:55 a.m.	Program Overview and the Review Process Mr. Kenneth O. Olsen
10:30 a.m.	Coffee Break
10:45 a.m.	Status of Substitute Chemical Reviews Ms. Linda McIntyre
11:00 a.m.	Regional Participation Mr. Richard Walka
11:30 a.m.	Registrant Overview Dr. Richard C. Back
12:00 Noon	Lunch
2:00 p.m.	Research Workshop Sessions 1. Toxicological Methods and Genetic Effects (Battlefield A Room) 2. Ecosystems/Modeling (Battlefield B Room) 3. Chemical Methods (Lee Room)
7:00 p.m.	Cash Bar
8:00 p.m.	Buffet Dinner Substitute Chemical Program Mr. John R. Quarles, Jr.

Note: Not all speeches available for publication

Plenary Session (continued)

Thursday, July 31, 1975

8:30 a.m.) to) 3:30 p.m.)	Research Workshop Sessions (continued)
	New Generation Pesticides - Mr. Kenneth O. Olsen, Chairperson
3:30 p.m.	Rapid Screening, Mode of Action, and Information to Develop Guidelines for the Registration of New Generation Pesticides Dr. William G. Phillips
4:15 p.m.	Commercial Feasibility of New Generation Pesticides Dr. Peter D. Stent
5:00 p.m.	Dinner
7:30 p.m.	Continuation of Research Workshop Session 1

Friday, August 1, 1975

	Mr. Kenneth O. Olsen, Chairperson
8:30 a.m.	Linear Programming Model of U. S. Agriculture Mr. Fred Arnold
	Mathematical Linear Programming Mr. Stanley Hargrove
	Integrated Pest Management Dr. Kenneth J. Hood
10:00 a.m.	Coffee Break
10:15 a.m.	Research Progress Sessions Chairpersons' Reports
12:00 Noon	Adjournment

TOXICOLOGICAL METHODS AND GENETIC EFFECTS WORKSHOP

AGENDA

Wednesday, July 30, 1975

Dr. August Curley and Dr. Lamar B. Dale, Jr., Chairpersons

2:00 p.m. Introduction
Dr. August Curley

Inhalation Studies

2:10 p.m. Inhalation Toxicology of Substitute Chemicals
Dr. James T. Stevens

2:40 p.m. Inhalation Toxicology
Dr. Gordon W. Newell

3:10 p.m. Studies on Toxicity to Mammals of Small Particle Aerosols of Nuclear Polyhedrosis Virus (NPV) Pesticides
Dr. James T. Stevens

3:20 p.m. Metabolism of Pesticides
Dr. Ronald L. Baron

3:30 p.m. Discussion: Inhalation Toxicology

3:45 p.m. Coffee Break

Acute, Subacute, and Chronic Studies

4:00 p.m. Toxicological Evaluations
Dr. Ralph I. Freudenthal

4:10 p.m. Toxicological Research: Acute LD_{50} Studies
Dr. Larry L. Hall

4:20 p.m. 2-AAF as a Model Compound
Dr. Thomas J. Haley

4:45 p.m. A Study of Age Sensitivity to the Chemical Carcinogen 2-Acetylaminofluorene
Dr. David L. Greenman

TOXICOLOGICAL METHODS AND GENETIC EFFECTS WORKSHOP (continued)

Acute, Subacute, and Chronic Studies (continued)

5:10 p.m.	Benchmark Toxicity Dr. Lawrence Fishbein
5:20 p.m.	Pharmacokinetic Modeling of Select Pesticides Dr. John F. Young
5:30 p.m.	Discussion: Acute, Subacute, and Chronic Studies
5:45 p.m.	Adjournment

Thursday, July 31, 1975

8:30 a.m.	Pesticide Residues in Human Milk Dr. Eldon P. Savage
8:50 a.m.	Effect of Substitute Pesticides in Hormone-Dependent Tissue Dr. Sydney A. Shain
9:10 a.m.	Effects of Pesticides on Blood Lipoproteins, Arteries, and Cardiac Muscle Dr. Jack E. Wallace
9:30 a.m.	Fetal Tissue Analysis for Pesticide Residues Dr. Irwin Baumel
9:40 a.m.	Discussion
9:55 a.m.	Coffee Break

Carcinogenic and Teratogenic Tests

10:15 a.m.	Introduction Dr. Morris F. Cranmer
10:30 a.m.	*In Vitro and In Vivo* Carcinogenic and Mutagenic Screen Development Dr. Erling M. Jensen
10:45 a.m.	Drosophila Mutagenesis Tests Dr. Ruby Allen Valencia

TOXICOLOGICAL METHODS AND GENETIC EFFECTS WORKSHOP (continued)

Carcinogenic and Teratogenic Tests (continued)

11:05 a.m. *In Vitro* and *In Vivo* Studies of Selected Pesticides to Evaluate Their Potential as Chemical Mutagens
Dr. Gordon W. Newell

11:20 a.m. Unscheduled DNA Synthesis Testing of Substitute Pesticides
Dr. Ann D. Mitchell

11:35 a.m. Mammalian Screens
Dr. Gordon W. Newell

11:50 a.m. Discussion

12:30 p.m. Lunch

Carcinogenic and Teratogenic Tests (continued)

1:30 p.m. Use of Mutagenesis Test to Indicate Carcinogenesis
Dr. Barry Commoner

2:00 p.m. Criteria for Comparison of Teratogenesis Protocols
Dr. Herbert J. Schumacher

2:25 p.m. Adjournment

Thursday Night, July 31, 1975

Dr. Morris F. Cranmer, Chairperson

7:30 p.m. Feasibility Study: Detection of Chemical-Induced Mutation by Assay of Metabolic Characteristics
Dr. Harvey W. Mohrenweiser

7:45 p.m. Feasibility Study: The Use of Diploid Cell Strains from Specified Mouse Genotypes for Use in Developing *In Vitro* Assay for Mutagenic Activity, Induction, and Analysis of Gene Mutations in Mammalian Cell Lines
Dr. Daniel A. Casciano

TOXICOLOGICAL METHODS AND GENETIC EFFECTS WORKSHOP (continued)

8:00 p.m.	Epidemiology of Pesticides: Cancer Mortality and Pesticide Usage in the United States Dr. William F. Durham
8:20 p.m.	Effects of Cacodylic Acid on the Prenatal Development of Rats and Mice Dr. Neil Chernoff
8:35 p.m.	Assessment of Subtle and Delayed Effects of Substitute Chemicals Dr. Daniel A. Spyker
8:50 p.m.	Adjournment

ECOSYSTEMS/MODELING WORKSHOP

AGENDA

Wednesday, July 30, 1975

Dr. John L. Buckley and Dr. Norman R. Glass, Chairpersons

2:00 p.m.	Opening Remarks Dr. John L. Buckley
2:10 p.m.	Review of Whole Program Status and Direction of Future NERL Programs Dr. Norman R. Glass
2:20 p.m.	Progress and Status Report on Terrestrial In-House System Dr. James W. Gillett
2:40 p.m.	Progress and Status Report on Terrestrial Microcosm Development Dr. James R. Sanborn
3:00 p.m.	The Effects of Mirex on the Predator-Prey Interactions in an Experimental Estuarine Ecosystem Dr. W. Peter Schoor
3:15 p.m.	Effects of Mirex on the Burrowing Activity of the Lugworm (*Arenicola cristata*) Dr. W. Peter Schoor
3:30 p.m.	Coffee Break
3:45 p.m.	Progress and Status Report on Fresh Water Ecosystem Methodology Development Dr. Allen R. Isensee
4:05 p.m.	Review of Research Plan for Whole Systems Model - Design, Validation, and Integration Between Terrestrial and Aquatic Environment Dr. Erik D. Goodman
4:15 p.m.	Mathematical Modeling of Pesticide Fate Dr. James W. Gillett

ECOSYSTEMS/MODELING WORKSHOP (continued)

4:35 p.m.	Effects of Pesticide Use Patterns on the Incidence of Plant Disease and on Patterns of Pesticide Degradation Mr. John Bowser
4:45 p.m.	Benchmark Chemistry Program Dr. Riz Haque
5:05 p.m.	Development of Rapid Screening Techniques for Herbicide Phytotoxicity Dr. Fumihiko Hayashi

Thursday, July 31, 1975

8:30 a.m.	Program of the Office of Toxic Substances in Relation to Microcosm Methodology Development, and Ecological Effects Program of the Office of Toxic Substances Ms. Carter Schuth
8:50 a.m.	Analytical Methods Development Dr. James Hill
9:20 a.m.	Special Interest Topics and General Discussion
12:15 p.m.	Lunch
1:30 p.m.	Special Interest Topics and General Discussion
2:25 p.m.	Adjournment

CHEMICAL METHODS WORKSHOP

AGENDA

Dr. Edward O. Oswald and Dr. Gunter Zweig,
Chairpersons

Wednesday, July 30, 1975

2:00 p.m.	Introduction Dr. Edward O. Oswald
2:10 p.m.	Microelectrolytic Conductivity Detector Mr. Jack B. Dixon
2:40 p.m.	Discussion
2:50 p.m.	Multiresidue Methodology Dr. H. Anson Moye
3:20 p.m.	Discussion
3:30 p.m.	Identification of Impurities in Technical-Grade Pesticides Dr. J. S. Warner
4:00 p.m.	Discussion
4:10 p.m.	Coffee Break
4:25 p.m.	Chemical Methods Introduction Dr. Gunter Zweig
4:35 p.m.	Sensory Chemical Pesticide Warning System Dr. Donald E. Johnson
5:05 p.m.	Discussion
5:15 p.m.	Hyperfine Labeling Techniques Dr. Barry Commoner

Thursday, July 31, 1975

8:30 a.m.	Chemical Methodology Introduction Dr. Edward O. Oswald
8:40 a.m.	Mass Spectrometry Methods Development Dr. Edward O. Oswald

CHEMICAL METHODS WORKSHOP
(continued)

9:10 a.m.	Discussion
9:20 a.m.	Automated Cleanup and Specific Detector System for Pesticide Residue Analysis Dr. Kenneth R. Hill
9:35 a.m.	Discussion
9:40 a.m.	Multiresidue Methodology Dr. Robert Moseman
9:55 a.m.	Discussion
10:00 a.m.	Pesticides in Ambient Air Dr. Robert Lewis
10:15 a.m.	Coffee Break
10:35 a.m.	*In Situ* Method for Organophosphate Insecticides Dr. William T. Colwell
10:50 a.m.	Discussion
10:55 a.m.	Toxic Potentiators as By-Products of Organophosphorus Insecticides Dr. R. Fukuto
11:10 a.m.	Discussion
	Intramural Programs
11:15 a.m.	Research Programs of the Chemistry Branch Dr. Edward O. Oswald
1:00 p.m.	Special Interest Topics and General Discussion
3:10 p.m.	Adjournment

APPENDIX II

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